EXHIBIT 8

FDA Briefing Document
Oncology Drugs Advisory Committee Meeting

July 24, 2007

NDA 21801 Orplatna® (satraplatin capsules)

APPLICANT GPC Biotech

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PROPOSED INDICATION

"For the treatment of patients with androgen independent (hormone refractory) prostate cancer (HRPC) that has failed prior chemotherapy"

EXECUTIVE SUMMARY

The pivotal study for this NDA is the SPARC study in 950 patients sponsored by the Applicant. A small EORTC study in 50 patients is submitted as a supportive study.

The SPARC study is a multicenter, multinational, double blind placebo-controlled trial with 950 patients with androgen-independent prostate cancer that has failed one (and only one) prior chemotherapy regimen. Patients were randomized 2:1 to Orplatna plus prednisone or placebo plus prednisone. **Placebo patients were not crossed over to Orplatna after progression.** The primary efficacy endpoints are progression-free survival (PFS) and overall survival (OS). Progression events were adjudicated by a blinded independent committee of radiologists and oncologists.

The first issue is the definition of one of the two primary endpoints, PFS. PFS is defined as a composite endpoint, consisting of radiographic progression, symptomatic progression (pain, analgesics, ECOG performance status, weight loss and other clinical events related to prostate cancer) and skeletal related events. The FDA has no prior experience with this endpoint. This was clearly communicated to the Applicant during the development phase. FDA will seek ODAC advice on the acceptability of this composite PFS endpoint as the basis of marketing approval.

Orplatna was better than placebo on the composite PFS endpoint with median PFS 11.1 weeks versus 9.7 weeks (a median difference of 10 days) and HR 0.67 (0.57, 0.77). Orplatna was also better than placebo on PFS defined as only radiologic progression or death with median PFS 36.3 weeks and 20.0 weeks and HR 0.64 (0.51, 0.81). Whether this will translate to OS benefit is unknown at this time.

The second issue is that the two independent radiology readers disagreed on the progression status in 367 of the 950 patients (39%), requiring adjudication by a third independent radiology reader. This raises the question whether PFS could be reliably assessed in this clinical trial.

The third issue regards the assessment of pain progression. Note that pain progression is both part of the composite PFS co-primary endpoint and also the basis for the secondary endpoint of time to pain progression. Because of Orplatna toxicities, it is unlikely that blinding was maintained. . In addition, based on a review of background materials provided by the Applicant describing the methods for assessing pain intensity in the SPARC Study, the FDA has determined that the single item Present Pain Intensity Scale

(PPI), derived from the McGill Pain Questionnaire (MPQ), has not been adequately validated for use in this study. The MPQ PPI instrument was used a decade ago in the approval of mitoxantrone for treatment of HRPC, but different criteria for pain response and pain progression were used. Also in the mitoxantrone study the primary endpoint was reduction in pain intensity, while in the Orplatna study the main pain endpoint is time to pain progression. Finally, the FDA Center for Drug Evaluation and Research standards for pain assessment have changed in the interval. In addition, the SPARC protocol did not specify any plan for pain management and pain progression based on increased analgesic use varied widely between countries. Non-narcotic pain medicine usage was not considered in determining pain progression.

The fourth issue is that only 51% of patients had prior docetaxel. Docetaxel is the only drug shown to improve survival in patients with HRPC. All patients should have had prior docetaxel. However, the SPARC trial was started before FDA approval of docetaxel for this use. Subgroup analyses in patients with and without prior docetaxel show that the Orplatna PFS advantage is maintained in both subgroups. Whether there will be a survival advantage in the subgroup with prior docetaxel remains to be seen.

The fifth issue is whether the FDA should wait for the final survival analysis before taking action on the Orplatna application. An interim analysis of overall survival after 463 deaths does not show that Orplatna is better than placebo. The final analysis of overall survival will occur when there are 700 deaths which is estimated to be near the end of 2007.

The main Orplatna toxicity is hematologic with grade 3-4 neutropenia in 21.1% of patients and grade 4 neutropenia in 4.1% of patients. Infectious episodes occurred in 23.7% of Orplatna patients compared to 11.5% of placebo patients. Grade 3-4 thrombocytopenia occurred in 21.8% of Orplatna patients. Only 2 (0.3%) Orplatna patients had grade 4 thrombocytopenia. Gastrointestinal disorders including nausea, vomiting and diarrhea occurred in 58.5% and 29.1% of Orplatna and placebo patients, respectively. Only 1.9% of Orplatna patients had grade 3-4 diarrhea and 1.6% had grade 3-4 vomiting.

Of note, 14 (2.2%) patients with renal failure were reported in the Orplatna group versus 2 (0.6%) in the placebo group. Serum creatinine elevations were seen in 20.9% (62/313) of the patients in the placebo group and 17.0% (102/629) of the patients in the Orplatna group. A potential interaction between severe hepatic impairment and development of acute renal failure was suggested by a pharmacokinetic study in which 2 of 5 patients with severe hepatic impairment (Child-Pugh Class C) experienced acute renal failure following 1 or more cycles of Orplatna 80 mg/m^2 dx5 q35d. The safety and efficacy of Orplatna in patients with moderate to severe renal impairment, determined by (calculated) creatinine clearance <50 mL/min, have not been established. Biochemical markers for renal function (creatinine and BUN) and hepatic function should be monitored prior to initiating each cycle of treatment and as appropriate.

The EORTC study of similar design to the SPARC study, but in a different patient population (initial chemotherapy in patients with HRPC), was stopped after 50 patients were accrued and provides little support for this NDA.

Recommendation is deferred pending ODAC advice on the above issues.

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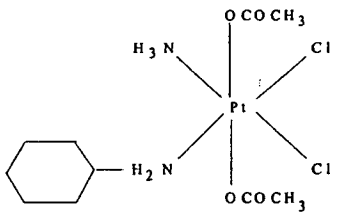
DRUG DESCRIPTION

Orplatna contains satraplatin, which is an organo-platinum complex described chemically as *(OC-6-43)* bis (acetato) amminedichloro (cyclohexylamine) platinum (IV). The molecular formula is $C_{10}H_{22}Cl_2N_2O_4Pt$ and the molecular weight is 500.3. The structural formula is:



Formulation: Orplatna 10 mg and 50 mg capsules for oral administration.

CLINICAL PHARMACOLOGY

Pharmacokinetics

Absorption: After oral administration of a single 80 mg/m^2 Orplatna dose in the fasting state, satraplatin is rapidly absorbed with peak platinum levels occurring 1-4 hours after dosing. Administration of Orplatna after a high fat meal results in a 26% decrease in peak platinum plasma ultra-filtrate concentrations and an 8% decrease in platinum ultra-filtrate AUC.

Distribution: Linear pharmacokinetics are seen at Orplatna oral doses up to 120 mg/m^2. Increase in platinum AUC or peak concentration was not seen with increases in Orplatna oral doses above 200 mg/m^2. After dosing of Orplatna 80 mg/m^2 daily orally for 5 consecutive days the apparent half-life of platinum is approximately 10 days. Orplatna dosing of 80 mg/m^2 once daily for 5 consecutive days results in platinum accumulation ratios of 1.5 and 3 in plasma and plasma ultrafiltrate.

Satraplatin binds irreversibly to serum proteins. Binding of platinum increases as a function of time after oral dosing from 50% at 30 minutes after dosing to approximately 90% at ten hours after dosing.

Metabolism: Satraplatin is extensively metabolized by erythrocytes as well as hepatic enzymes. After 5 consecutive days of Orplatna single oral doses of 80 mg/m^2, no unchanged satraplatin is detected in plasma ultrafiltrate. The only active metabolite identified is a platinum (II) complex that represents 20-30% of the total platinum in plasma ultra-filtrate. The remaining platinum-containing moieties in plasma ultrafiltrate have not been identified. Clinical safety and effectiveness do not show a relationship to platinum ultra-filtrate levels. The major route of platinum elimination in animal studies appears to be renal.

Drug Interactions

Clinical drug interaction studies were not conducted. Satraplatin has been shown *in vitro* to inhibit multiple human cytochrome P450 isoenzymes, including 2D6, 2C9, 3A4 and 1A2. Orplatna may cause an increase in the blood level of drugs that are substrates for cytochrome P450 enzymes.

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SPARC STUDY

Study Design

The SPARC study is a multicenter, multinational, double blind placebo-controlled trial with 950 patients with androgen-independent prostate cancer that has failed one (and only one) prior chemotherapy regimen. Patients were randomized 2:1 to Orplatna plus prednisone or placebo plus prednisone. **Placebo patients were not crossed over to Orplatna after progression.** The primary efficacy endpoints are (PFS) and overall survival (OS). Progression events were adjudicated by a blinded independent committee of radiologists and oncologists. Randomization was stratified according to:

- Eastern Cooperative Oncology Group (ECOG) performance status (0-1 *vs.* ≥2);
- Average baseline Present Pain Intensity (PPI) score (0-1 *vs.* 2-5);
- Type of progression on prior chemotherapy (PSA progression only *vs.* tumor progression; patients with both rising PSA and tumor progression were included as tumor progression).

Treatment

For each treatment cycle the dosing schedule was as follows:

Days 1-5:

- Prednisone 5 mg and antiemetic (granisetron or placebo) 1 mg, administered orally 1 hour prior to Orplatna;
- Study medication (Orplatna or placebo) 80 mg/m² orally, while fasting (at least 1 hour before a meal or 2 hours after a meal);
- Prednisone 5 mg and antiemetic (granisetron or placebo), administered orally 8 hours after dosing study medication (Orplatna or placebo).

Days 6-35:

- Prednisone 5 mg in AM and 5 mg in PM.

Definition of Disease Progression

Disease progression was defined as a composite endpoint based on the first occurrence of the following:

Radiographic progression, based on RECIST criteria for soft tissue lesions and bone scans for bone lesions. Progression was defined as either a ≥ 20% increase in the sum of the longest diameter of target lesions, taking as reference the smallest sum of the longest diameters recorded since treatment initiation, or unequivocal progression of existing non-target lesions or the appearance of one or more new lesions (or reappearance of any

target lesions that had disappeared), with the following exceptions:

- In cases for which initial tumor flare reaction was possible (e.g., hypercalcemia, increased bone pain, erythema of skin lesions), either symptoms had to persist beyond 4 weeks or additional evidence of progression was required;
- Lesions that appeared to increase in size due to presence of necrotic tissue were not considered to have progressed;
- Intensity changes on bone scans were not used to determine progression, as increased uptake does not constitute unequivocal progression;
- Progression by bone scan alone required two or more lesions; if only one new lesion was documented, the lesion must have been confirmed as being cancerous by additional radiographic studies, starting with a plain radiograph and then followed up with MRI and/or CT scans if the plain radiograph was non-diagnostic; and
- New lesions on bone scan in the presence of improvement of PSA and/or symptoms were not to be considered progressive disease.

Skeletal related events, defined by any observation of the following:

- pathologic bone fracture in the region of cancer involvement;
- radiation therapy to bone;
- cancer related surgery to bone;
- spinal cord or nerve root compression;
- initiation of bisphosphonate therapy in response to new bone pain symptoms; or
- change of antineoplastic therapy for bone pain due to prostate cancer.

Symptomatic progression, defined by observation of any of the following:

- Increase in pain, defined by either an increase in Present Pain Intensity (PPI) score of at least one point from baseline or at least two points compared with the nadir, observed for at least 2 weeks (based on 2 or more consecutive weekly PPI determinations) OR an increase of greater than 25% in weekly average analgesic score maintained for a minimum of 2 consecutive weeks.
  Disease-related pain was followed by a patient diary that recorded pain using the 6-point PPI scale (0=no pain to 5=excruciating pain) of the McGill-Melzack questionnaire and analgesic use on a daily basis, as well as the name, strength, and number of pills or doses used each day. A daily analgesic score was calculated using a numeric scale. A standard dose of narcotic medication was scored as 2 units and higher doses were scored proportionally (e.g., 10 mg morphine = 2 units, 20mg morphine =4 units).
- An increase in ECOG performance status of 2 or more units compared with baseline, attributable to cancer in the investigator's opinion and confirmed by a history exceeding two weeks.
- Weight loss of greater than 10% of initial body weight (taken at last baseline measurement) attributable to cancer in the investigator's opinion; or
- Other clinical events attributable to prostate cancer in the investigator's opinion that required intervention, such as bladder outlet or ureteral obstruction or symptomatic spinal cord compression.

An increase in PSA was not part of this progression endpoint.

Efficacy Assessments

- Bone scans at baseline, after every 2 cycles of treatment for first 6 cycles, then every 3 cycles of treatment until 12 cycles, then every 6 cycles of treatment until disease progression
- CT/MRI scans of abdomen/pelvis and chest x-ray/CT scan at baseline. If positive, repeat every 2 cycles of treatment until disease progression
- Patient daily diaries of pain assessment (PPI score) and analgesic use
- Body weight at baseline and prior to each cycle of treatment;
- Performance status (PS) at baseline and prior to each cycle of treatment

Study Results

Statistical Plan

First Patient Randomized:	September 25, 2003
Last Patient Randomized:	January 5, 2006
Study Cut-Off Date for Efficacy Analyses:	June 15, 2006
Study Cut-off Date for Safety Analyses:	November 15, 2006

Initial estimated sample size was 912 patients to have 602 deaths within 36 months (24 months accrual and 12 months follow-up), providing 85% power to detect a 30% increase in median survival from 12 months in the placebo. It was later decided to increase the power to 90%, requiring 700 deaths.

For time to event endpoint (PFS, OS and time to pain progression) analyses the stratified Log Rank Test was used. Hazard ratios were derived using the stratified Cox. The pre-randomization stratification factors were used in both the stratified Log Rank Test and the stratified Cox.

Interim analysis of PFS was done on June 15, 2005 at 354 events and final analysis on June 15, 2006 at 802 events with a prespecified alpha of 0.0244. Final analysis of PFS was specified to be done at about 700 events, but 802 events were included. Interim analysis of survival was done at 463 events and final analysis will be done at 700 events with a prespecified alpha of 0.0444. The 700th survival event is estimated to occur in late 2007.

Enrollment by Country

Country	Number (%) of Sites	Number (%) of Patients
United States	75 (44.1%)	258 (27.2%)
France	17 (10.0%)	141 (14.8%)
Argentina	15 (8.8%)	98 (10.3%)
United Kingdom	10 (5.9%)	85 (8.9%)
Poland	7 (4.1%)	71 (7.5%)
Germany	12 (7.1%)	61 (6.4%)
Belgium	5 (2.9%)	46 (4.8%)
Spain	7 (4.1%)	42 (4.4%)
Others	22 (12.9%)a	148 (15.6%)b

[a] Others includes Canada (n=1 site), Croatia (n=2), Hungary (n=2), Israel (n=4), Italy (n=4), the Netherlands n=3), Peru (n=3), and Russia (n=3)
[b] Others includes Canada (n=3 patients enrolled), Croatia (n=24), Hungary (n=22), Israel (n=14), Italy (n=23), the Netherlands (n=11), Peru (n=23), and Russia (n=28)

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Demographic and Patient Characteristics: ITT Population

Demographic Characteristic	Number (%) of Patients		
	Satraplatin (N=635)	Placebo (N=315)	Total (N=950)
Age			
N	635	315	950
<65 years	180 (28.3)	93 (29.5)	273 (28.7)
>65 years	455 (71.7)	222 (70.5)	677 (71.3)
>75 years	167 (26.3)	85 (27.0)	252 (26.5)
Median (min-max)	70 (42-88) yr	68 (45-95) yr	70 (42-95) yr
Race			
Caucasian	559 (88.0)	282 (89.5)	841 (88.5)
Black	26 (4.1)	17 (5.4)	43 (4.5)
Latin American	43 (6.8)	13 (4.1)	56 (5.9)
Other d	7 (1.1)	3 (1.0)	10 (1.1)
ECOG Performance Status			
N	635	315	950
ECOG 0-1	570 (89.8)	283 (89.8)	853 (89.8)
ECOG 2	65 (10.2)	32 (10.2)	97 (10.2)
Average PPI Score			
N	635	315	950
PPI 0-1	410 (64.6)	204 (64.8)	614 (64.6)
PPI 2-5	225 (35.4)	111 (35.2)	336 (35.4)
Type of progression after prior chemo			
N	635	315	950
Tumor progression	392 (61.7)	195 (61.9)	587 (61.8)
PSA increase only	243 (38.3)	120 (38.1)	363 (38.2)
Alkaline phosphatase			
N	624	312	936
<1.5 x ULN	374 (58.9)	188 (59.7)	562 (59.2)
>1.5 x ULN	250 (39.4)	124 (39.4)	374 (39.4)
Hemoglobin			
N	633	315	948
>11.0 g/dL	491 (77.3)	253 (80.3)	744 (78.3)
<11.0 g/dL	142 (22.4)	62 (19.7)	204 (21.5)
Lactate dehydrogenase			
N	574	291	865
<2 x ULN	516 (81.3)	260 (82.5)	776 (81.7)
>2 x ULN	58 (9.1)	31 (9.8)	89 (9.4)
PSA			
N	630	313	943
Median (min-max) (ng/ml)	140 (0.1-6084)	134 (0.1-7059)	138 (0.1-7059)
Analgesic score			
N	617	299	916
Median (min-max)	0.0 (0.0-215)	0.0 (0.0-136)	0.0 (0.0-215)

Table continued on following page

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Demographic Characteristic	Satraplatin (N=635)	Placebo (N=315)	Total (N=950)
AUA staging at HRPC screening			
N	635	314	949
C2	1 (0.2)	0	1 (0.2)
D2	633 (99.7)	314 (99.7)	947 (99.7)
D3	1 (0.2)	0	1 (0.1)

Prior Chemotherapy*

	Satraplatin	Placebo	Total
Docetaxel	327 (51.5)	160 (50.8)	487 (51.3)
Paclitaxel	17 (2.7)	9 (2.9)	26 (2.7)
Mitoxantrone	128 (20.2)	64 (20.3)	192 (20.2)
Duration of prior chemotherapy			
N	635	315	950
Median (min-max)	20.6 weeks (0.4-381.6)	19.6 weeks (3.0-231.7)	20.4 weeks (0.4-381.6)

* Only prior taxane and mitoxantrone are shown; these do not include all patients, but significant overlap with combination regimens precluded simple treatment categories for other agents

PFS Events: Intent-to-Treat Population

	Number (%) of patients		
	Satraplatin (n=635)	Placebo (n=315)	Total (n=950)
PFS events, n/N (%)	528/635 (83.1%)	274/315 (87.0%)	802/950 (84.4%)
Radiographic progression	189/528 (35.8%)	101/274 (36.9%)	290/802 (36.2%)
Pain	181/528 (34.3%)	117/274 (42.7%)	298/802 (37.2%)
Performance status	15/528 (2.8%)	8/274 (2.9%)	23/802 (2.9%)
Weight	15/528 (2.8%)	7/274 (2.6%)	22/802 (2.7%)
Skeletal related events	22/528 (4.2%)	5/274 (1.8%)	27/802 (3.4%)
Other progressions [a]	58/528 (11.0%)	23/274 (8.4%)	81/802 (10.1%)
Deaths	48/528 (9.1%)	13/274 (4.7%)	61/802 (7.6%)

[a] includes patients receiving a new chemotherapy or steroids considered by the IRC as evidence of progression. In this table, percentages are based on numbers of patients with PFS events.
Modified Applicant Table

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PFS Overall and By Type of Event

Analysis	Satraplatin (N=635)	Placebo (N=315)
PFS – ITT Population		
PFS events, n (%)	528 (83.1%)	274 (87.1%)
Mean (SE)	24.9 (1.2) weeks	16.2 (1.2) weeks
Median	11.1 weeks	9.7 weeks
HR (95% CI)	**0.67 (0.57, 0.77) , p <0.001**	
ITT subset with radiologic progression or death*		
PFS events, n (%)	237 (37.3%)	114 (36.2%)
Mean (SE)	45.7 (2.1) weeks	32.3 (2.5) weeks
Median	36.3 weeks	20.0 weeks
HR (95% CI)	**0.64 (0.51, 0.81)**	
ITT subset with pain progression or death*		
PFS events, n (%)	229 (36.1%)	130 (41.3%)
Mean (SE)	53.0 (2.3) weeks	37.6 (2.9) weeks
Median	54.9 weeks	23.9 weeks
HR (95% CI)	**0.64 (0.51, 0.79)**	
ITT subset with other than radiologic and pain progression or death*		
PFS events, n (%)	158 (24.9%)	56 (17.8%)
Mean (SE)	58.0 (2.5) weeks	48.6 (3.5) weeks
Median	66.7 weeks	50.1 weeks
HR (95% CI)	**0.86 (0.63, 1.17)**	

HR: hazard ratio; CI: confidence interval; SD: standard deviation
*** It is to be noted that these include informed censoring. For example, a pain event was censored at the time of event in considering radiologic progression analysis.**
Modified Applicant Table

Adjudicated Radiologic Studies

Type of Progression	Number	Number Adjudicated	Percent Adjudicated
Radiologic Progression	291	136	46.7
Not Radiologic Progression	659	231	35.1
Total	950	**367**	**38.6**

As shown in the above Table, the 2 independent radiologic reviewers disagreed on the progression status of 38.6% (367 of 950) of the patients, requiring adjudication by a third radiologist. This raises the question whether progression could be reliably assessed in this trial.

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Time to Pain Progression

Analysis	Satraplatin (N=635)	Placebo (N=315)	p-value
Pain progression events, n (%)	217 (34.2%)	130 (41.3%)	<0.001a
Increase in cancer-related pain	114/217 (52.5%)	57/130 (43.8%)	
>25% increase in opioid analgesic use	103/217 (47.5%)	73/130 (56.2%)	
Mean (SE)	53.0 (2.3) weeks	36.6 (2.7) weeks	
Median	66.1 weeks	22.3 weeks	
HR (95% CI)	**0.64 (0.51, 0.79)**		<0.001b

HR: Hazard ratio, CI: confidence intervals, SE: standard error
[a] log-rank test
[b] Cox Proportional Hazards
Modified Applicant Table

The FDA Center for Drug Evaluation and Research (CDER) Study Endpoints and Labeling Development Team (SEALD) evaluated the methods used for assessing pain in the SPARC Study based on background materials provided by the sponsor. SEALD concluded that an increase in pain, defined by either an increase in Present Pain Intensity (PPI) score of at least one point from baseline or at least two points compared with the nadir, observed for at least 2 weeks (based on 2 or more consecutive weekly PPI determinations) *OR* an increase of greater than 25% in weekly average analgesic score maintained for a minimum of 2 consecutive weeks was an inadequate endpoint in measuring pain progression and should not be included in the composite primary endpoint of PFS. This assessment also applies to the secondary endpoint of time to pain progression.

The use of the PPI in the SPARC Study was justified by the Applicant based upon the precedent established by the pivotal studies supporting the approval of mitoxantrone plus prednisone for palliation of pain in HRPC (Tannock 1996) and docetaxel plus prednisone for the treatment of HRPC (Tannock 2004). However, in both Tannock studies (1996 & 2004), the primary endpoint was "pain palliation," and "pain progression" was a secondary endpoint. In addition, in both Tannock studies (Tannock 1996, Tannock 2004), criteria utilized for "pain progression" were different than the criteria used in the Orplatna SPARC study.

The Present Pain Intensity (PPI) has not been shown to be an adequate or validated measurement of pain progression as defined in the SPARC Study. The single item PPI was obtained from the original parent instrument, the McGill Pain Questionnaire (MPQ). The MPQ was specifically designed for researchers as an interview format and not designed for patient self-reporting. The original MPQ PPI item asked patients to rank their *worst* pain over the past 24 hours, while the PPI used in the SPARC Study asked patients to *average* their pain over 24 hours. The response options for the PPI (1–Mild; 2–Discomforting; 3–Distressing; 4–Horrible; 5–Excruciating) are problematic. There is inadequate evidence that these response options used to describe pain intensity (such as

"distressing") have content validity, can be converted to a numeric equivalent, and that the numbers can be averaged.

There has not been adequate evaluation of the measurement properties of either the PPI or the analgesic use scoring system used in the SPARC Study. Specifically, there has not been evaluation of reliability (test-retest properties, internal consistency, or inter-reviewer reliability), ability to detect change, content validity (i.e., evidence that patients understand terminology or that responses to items actually reflect the intended outcome), or construct validity (i.e., evidence that a measure can discriminate between clinically-defined patient groups). There is insufficient evidence to support the translation and cultural adaptation of the daily diary/pain instrument for use in the multinational SPARC Study.

The interpretation of scores has not been ascertained in order to determine if a 1 or 2 point change in PPI score or 25% change in opioid dose is clinically meaningful. (Is a change in pain score from none to mild or a 25% change of oxycodone dose from 10mg to 12.5mg clinically meaningful)? In considering if a 25% increase in narcotic analgesics is clinically important, if pain palliation is the intent, pain medication might be preferable to Orplatna.

In addition, the SPARC protocol did not specify any plan for pain management and pain progression based on increased analgesic use varied widely between countries. Non-narcotic pain medicine usage was not considered in determining pain progression. Given the toxicity of satraplatin, whether blinding was maintained is questionable.

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Interim Overall Survival*

Analysis	Satraplatin (N=635)	Placebo (N=315)	
Death events, n (%)	309 (48.7%)	154 (48.9%)	0.388[a]
Mean (SE)	61.8 (1.7) weeks	58.7 (2.3) weeks	
Median	61.3 weeks	57.3 weeks	
HR (95% CI)	0.90 (0.74, 1.09)		0.296[b]

***Placebo patients were not crossed over to Satraplatin after progression**
HR: Hazard ratio, CI: confidence intervals, SE: standard error
[a] log-rank test
[b] Cox Proportional Hazards model

Best Overall Tumor Response and Response Duration

	Satraplatin N=352[a]	Placebo N=177[a]	P Value
Best Overall Tumor Response (CR+PR)	23/352 6.5%	1/177 0.6%	P=0.001 Fishers Exact
Tumor Response Duration			
Mean	58.7 weeks	79.3 weeks	N/A
Median	53.3 weeks	79.3 weeks	

[a] number of patients with soft tissue lesions at baseline

Pain Response and Response Duration

	Satraplatin N=351[a]	Placebo N=181[a]	P Value
Best Overall Pain Response (CR+PR)[b]	85 (24%)	25 (14%)	P=0.005 Fishers Exact
Duration of Pain Response			P= 0.070[c]
Mean	39.1 weeks	24.1 weeks	
Median	33.6 weeks	19.7 weeks	
HR (95% CI)	0.62 (0.36, 1.07)		P=0.084[d]

[a]Number of patients for whom baseline PPI score and analgesic use were determined with baseline PPI score 1-5, and who had at least 4 consecutive weekly assessments of PPI and analgesic score from the period after treatment initiation until discontinuation of study medication.
[b]Patients with ≥2 point reduction in weekly PPI score from baseline (complete loss of pain if baseline PPI score was <2.0), maintained for ≥5 consecutive weeks, in the setting of a stable or decreasing weekly analgesic score. A stable or decreasing analgesic score was defined as no more than 25% increase from the baseline score.
[c]Log Rank Test
[d]Cox Proportional Hazards model

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Analyses of ITT Population and Subgroup with Prior Docetaxel

Analysis	ITT Population		Prior Docetaxel	
	Satraplatin N=635	Placebo N=315	Satraplatin N=327	Placebo N=315
PFS events, n (%)	528 (83.1)	274 (87.0)	273 (83.5)	140 (87.5)
Mean (SE) weeks	24.9 (1.2)	16.2 (1.2)	23.3 (1.6)	14.4 (1.4)
Median (weeks)	11.1	9.7	10.1	9.1
Hazard ratio (95% CI)	0.67 (0.57, 0.77)		0.67 (0.54, 0.83)	
Time to pain progression				
Pain prog. events, n/N (%)	217 (34.2)	130 (41.3)	125 (38.2)	70 (43.8)
Cancer-related pain	114/217 (52.5)	57/130 (43.8)	63/125 (50.4)	26/70 (37.1)
Increase opioid use	103/217 (47.5)	73/130 (56.2)	62/125 (49.6)	44/70 (62.9)
Mean (SE) weeks	53.0 (2.3)	36.6 (2.7)	40.1 (2.0)	33.9 (4.2)
Median (weeks)	66.1	22.3	42.0	21.1
Hazard ratio (95% CI)	0.64 (0.51, 0.79)		0.66 (0.49, 0.89)	
Interim Analysis on Overall survival				
Death events, n (%)	309 (48.7)	154 (48.9)	149 (45.6)	72 (45.0)
Mean (SE) weeks	61.8 (1.7)	58.7 (2.3)	62.3 (2.4)	59.2 (3.4)
Median (weeks)	61.3	57.3	64.0	61.9
Hazard ratio (95% CI)	0.90 (0.74, 1.09)		0.88 (0.67, 1.17)	

CI: confidence intervals, SE: standard error
Modified Applicant Table

FDA ODAC Orplatna Briefing Document

Drug Exposure [a]

Satraplatin/Placebo Administration		
Total duration of treatment		
Median	20.4 weeks	10.3 weeks
(min-max)	(4.6 – 170.4)	(4.7 – 100.6)
Number of treatment cycles per patient, Median (min-max)	4 (1-32)	2 (1-19)
Total cumulative dose (mg)		
Median	2600 mg	1700 mg
(min-max)	(260 – 33200)	(400 – 19050)
Relative dose intensity (%) Median	93.8%	96.4%
(min-max)	(41.5 – 142.5)	(50.0 – 154.7)
Number (%) patients with		
Dose reduction (<70 mg/m2)	132 (21.0%)	1 (0.3%)
Dose increase (>90 mg/m2)	51 (8.1%)	32 (10.2%)
Dose delay ≥7 days	279 (44.4%)	33 (10.5%)
Prednisone Administration		
Total duration of treatment		
Median	19.0 weeks	10.4 weeks
(min-max)	(0.1 – 166.0)	(0.4 – 95.9)
Number of cycles per patient, median (min-max)	4 (1-32)	2 (1-19)
Total cumulative dose (mg)		
Median	1270 mg	730 mg
(min-max)	(5 – 11620)	(25 – 6710)
Number (%) patients with		
Dose reduction (<5 mg)	217 (34.5%)	100 (31.9%)
Dose increase (≥15 mg)	5 (0.8%)	1 (0.3%)
Interrupted cycle	55 (8.7%)	12 (3.8%)
Granisetron/Placebo		
Number of cycles per patient Median (min-max)	4 (1-32)	2 (1-19)
Total cumulative dose (mg) Median (min-max)	39 mg (1 – 320)	20 mg (5 - 160)

[a]Doses administered after 15 November 2006 cut-off-date for analysis were not summarized.
max: maximum; min: minimum
Modified Applicant Table

The cut-off date for the safety analyses is November 15, 2006.

The satraplatin group had greater exposure to study drug than the placebo group, based on a median of 4 cycles (range: 1-32) compared to 2 cycles (range: 1-19) of treatment,

respectively. Satraplatin median dose intensity was 93.8% and Placebo 96.4% relative to the planned dose.

Both the satraplatin and placebo groups had equivalent daily doses (10 mg/day) of prednisone. However, the total median exposure to prednisone was 1.7-fold higher for the satraplatin group compared to the placebo group (1270 *vs.* 730 mg), consistent with the median of 4 vs. 2 cycles of treatment for the satraplatin and placebo groups, respectively.

The Applicant tries to make the point that since only the satraplatin group was exposed to active antiemetic and also had double the exposure to prednisone, the safety profile for satraplatin also reflects adverse effects from the antiemetic and prednisone. This is a mute point because the antiemetic is necessary with satraplatin and prednisone is also considered a necessary part of the regimen. The adverse effects seen in this trial are to be expected with general use of the satraplatin regimen.

Treatment-emergent adverse events (TEAEs) resulting in **dose reductions** for study drug were reported for 102 (16.2%) patients in the satraplatin arm and 2 (0.6%) patients in the placebo arm. The majority of dose reductions in the satraplatin arm (78% or 80/102) were due to myelosuppression. TEAEs resulting in **delayed dosing** of study drug (i.e., delays in initiating the subsequent cycle of therapy) were reported for 220 (35.0%) patients in the satraplatin arm and 14 (4.5%) patients in the placebo arm. Overall, myelosuppression was reported as reason for study drug delay in 86.8% (191/220) of the patients who experienced delayed dosing in the satraplatin arm. TEAEs resulting in **discontinuation** of study drug (satraplatin or placebo) were reported for 123 (13.1%) patients, 90 (14.3%) in the satraplatin arm and 33 (10.5%) in the placebo arm.

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Hematologic Toxicity

	Number (%) of Patients			Number (%) of Cycles		
Lab Toxicity	**Satraplatin N=629**	**Placebo N=313**	**p-value[a]**	**Satraplatin N=3199**	**Placebo N=1179**	**p-value[a]**
Hemoglobin						
All Grades	605 (96.2%)	282 (90.1%)	<0.001	2827 (88.4%)	824 (69.9%)	<0.001
Grades 2-4	271 (43.1%)	71 (22.7%)	<0.001	716 (22.4%)	110 (9.3%)	<0.001
Grades 3-4	59 (9.4%)	10 (3.2%)	<0.001	91 (2.8%)	13 (1.1%)	<0.001
Grade 4	11 (1.7%)	2 (0.6%)	NS	13 (0.4%)	2 (0.2%)	NS
Platelets						
All Grades	550 (87.4%)	62 (19.8%)	<0.001	2255 (70.5%)	131 (11.1%)	<0.001
Grades 2-4	278 (44.2%)	9 (2.9%)	<0.001	693 (21.7%)	9 (0.8%)	<0.001
Grades 3-4	137 (21.8%)	4 (1.3%)	<0.001	265 (8.3%)	4 (0.3%)	<0.001
Grade 4	2 (0.3%)	0		2 (0.1%)	0	NS
Leukocytes						
All Grades	480 (76.3%)	43 (13.7%)	<0.001	1732 (54.1%)	91 (7.7%)	<0.001
Grades 2-4	302 (48.0%)	7 (2.2%)	<0.001	686 (21.4%)	10 (0.8%)	<0.001
Grades 3-4	86 (13.7%)	2 (0.6%)	<0.001	117 (3.7%)	3 (0.3%)	<0.001
Grade 4	6 (1.0%)	0		6 (0.2%)	0	NS
Neutrophils						
All Grades	420 (66.8%)	15 (4.8%)	<0.001	1224 (38.3%)	23 (2.0%)	<0.001
Grades 2-4	295 (46.9%)	5 (1.6%)	<0.001	608 (19.0%)	8 (0.7%)	<0.001
Grades 3-4	133 (21.1%)	2 (0.6%)	<0.001	190 (5.9%)	3 (0.3%)	<0.001
Grade 4	26 (4.1%)	0	<0.001	28 (0.9%)	0	<0.001

[a]p-values calculated by Fisher's exact test. Caution should be used in interpreting p-values, as the intrapatient laboratory values may not be independent and there is no adjustment for multiple testing.
NS: not significant
Modified Appicant Table

Transfusions

Transfusion	Number (%) of Patients		Number (%) of Cycles	
	Satraplatin (N=629)	**Placebo (N=313)**	**Satraplatin (N=3199)**	**Placebo (N=1179)**
Red blood cells	102 (16.2)	25 (8.0)	171 (5.3)	32 (2.7)
Platelets	25 (4.0)	1 (0.3)	25 (0.8)	1 (0.1)

FDA ODAC Orplatna Briefing Document

Treatment Emergent Non-Hematologic Adverse Events Per Patient With Significantly Higher Incidence in Patients Receiving Satraplatin

	Number of patients-Worst Grade Reported [a]					
	All Grades			Grade 3-4		
Medra System Organ Class & Preferred Term	Satraplatin N=629	Placebo N=313	p-value [b]	Satraplatin N=629	Placebo N=313	p-value [b]
Patients with any TEAE	578 (91.9%)	259 (82.7%)	<0.001	343 (54.5%)	94 (30.0%)	<0.001
Gastrointestinal disorder	368 (58.5%)	91 (29.1%)	<0.001	49 (7.8%)	7 (2.2%)	<0.001
Constipation	144 (22.9%)	34 (10.9%)	<0.001	12 (1.9%)	3 (1.0%)	NS
Diarrhea NOS	156 (24.8%)	19 (6.1%)	<0.001	12 (1.9%)	0	0.011
Nausea	183 (29.1%)	34 (10.9%)	<0.001	8 (1.3%)	1 (0.3%)	NS
Vomiting	104 (16.5%)	28 (8.9%)	<0.001	10 (1.6%)	0	0.036
General disorders & admin. site conditions	276 (43.9%)	107 (34.2%)	0.005	50 (7.9%)	20 (6.4%)	NS
Asthenia	96 (15.3%)	29 (9.3%)	0.011	21 (3.3%)	5 (1.6%)	NS
Fatigue	115 (18.3%)	35 (11.2%)	0.005	11 (1.7%)	4 (1.3%)	NS
Infections & infestations	149 (23.7%)	36 (11.5%)	<0.001	28 (4.5%)	3 (1.0%)	0.003
Influenza	9 (1.4%)	0	0.034	0	0	NS
Upper respiratory tract infection NOS	17 (2.7%)	2 (0.6%)	0.046	0	0	NS
Investigations						
AST increased	15 (2.4%)	1 (0.3%)	0.028	0	0	NS
Metabolism & nutrition disorders	138 (21.9%)	43 (13.7%)	0.003	24 (3.8%)	9 (2.9%)	NS
Anorexia	80 (12.7%)	26 (8.3%)	0.049	4 (0.6%)	2 (0.6%)	NS
Appetite decreased	15 (2.4%)	1 (0.3%)	0.028	0	0	NS
Respiratory, thoracic & mediastinal disorders	123 (19.6%)	34 (10.9%)	<0.001	20 (3.2%)	5 (1.6%)	NS
Cough	38 (6.0%)	7 (2.2%)	0.009	0	0	NS
Dyspnea	45 (7.2%)	11 (3.5%)	0.028	6 (1.0%)	3 (1.0%)	NS
Pulmonary embolism	10 (1.6%)	0	0.036	5 (0.8%)	0	NS
Skin & subcutaneous tissue disorders	89 (14.1%)	32 (10.2%)	NS	6 (1.0%)	0	NS
Alopecia	13 (2.1%)	1 (0.3%)	0.043	0	0	NS
Vascular disorders	74 (11.8%)	20 (6.4%)	0.011	16 (2.5%)	3 (1.0%)	NS
Deep vein thrombosis	10 (1.6%)	0	0.036	4 (0.6%)	0	NS

[a]NCI Common Toxicity Criteria for Adverse Events Version 2.0 [b]p-values calculated by Fisher's exact test. Caution should be used in interpreting p-values, as the intrapatient laboratory values may not be independent and there is no adjustment for multiple testing.
NS: not significantly different. Modified Applicant Table

EORTC STUDY

In this international multi-center, randomized, open-label trial (EORTC study), 50 patients with advanced HRPC who **had not received prior chemotherapy** were randomized to treatment with Orplatna (100 mg/m^2 dx5 days q35d) and prednisone (10 mg bid daily for 35 days) **(n=27)** or prednisone alone 10 mg bid daily for 35 days **(n=23)**. Randomization was stratified for institution, analgesic use (yes *vs.* no), and presence *vs.* absence of clinically evaluable disease. Co-primary endpoints were time to pain progression and overall survival. Secondary endpoints were pain response rate, time to overall progression (TTP), objective response rate and duration of response, PSA response rate, and quality of life assessment. **Confirmed doubling from baseline of PSA to > 20 was a component of the overall progression criteria.**

The treatment groups were balanced for age (median 72.5 years *vs.* 70.4 years for the Orplatna *vs.* prednisone alone groups, respectively), WHO performance status (30% *vs.* 44% WHO 0; 39% *vs.* 37% WHO 1; 30% *vs.* 19% WHO 2), and baseline hematology and serum chemistry parameters.

The study was stopped after accruing only 50 of 380 planned patients because the previous Sponsor terminated their development program. Due to premature termination the study was underpowered. The median progression-free survival was 5.2 vs. 2.5 months for the Orplatna/prednisone and prednisone alone arms, respectively, HR=0.50 (95% CI: 0.28, 0.92).

The difference between treatment groups in overall survival was not significant with median of 14.9 months for Orplatna/prednisone vs. 11.9 months for prednisone alone, HR=0.84 (95%CI: 0.46, 1.55). Because the study was stopped prematurely, assessment of PPI pain scores was stopped and planned endpoints of time-to-pain progression and pain response and pain progression could not be assessed. All the results of this trial are to be interpreted with caution due to very small sample size and very few events.

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EORTC Study Results

Analyses	Satraplatin+Prednisone N=27	Prednisone alone N=23
Overall Survival		
Events	23/27 (85.2%)	19/23 (82.6%)
Median (95% CI)	14.9 months (13.7 – 28.4)	11.9 months (8.4 – 23.1)
HR (95% CI)	0.84 (0.46, 1.55)	
Progression-Free Survival[a]		
Events	25/27 (92.6%)	23/23 (100%)
Median (95% CI)	5.2 months (2.8 – 13.7)	2.5 months (2.1 – 4.7)
HR (95% CI)	0.50 (0.28, 0.92)	
Time to Progression[b]		
Events	25/27 (92.6%)	22/23 (95.7%)
Median (95% CI)	5.2 months (2.8 – 13.7)	2.5 months (2.1 – 4.7)
HR (95% CI)	0.53 (0.29, 0.98)	
Biochemical PFS[c]		
Events	25/27 (92.6%)	23/23 (100%)
Median (95% CI)	3.5 months (1.3-8.5)	2.3 months (1.3-2.8)
HR (95% CI)	0.58 (0.32, 104)	

[a]PSA response was included as a component of Progression-Free Survival
[b]Overall progression was defined as the first to occur of (1) ≥1 point increase in PPI score from baseline, confirmed by history exceeding 2 weeks of the requirement for radiation therapy for disease-related pain symptoms; (2) ≥2 point worsening in performance status compared to baseline, confirmed by a history exceeding 2 weeks; (3) progression of measurable or non-measurable disease; and (4) confirmed doubling of PSA to >20 ng/mL, as compared to baseline.
[c] Biochemical PFS defined as time to PSA progression or progression or death
Modified Applicant Table

GPC Biotech AG (GPCB)

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25-Jul-07	13.35	14.00	13.05	13.16	559,800	13.16
24-Jul-07	20.75	20.75	20.10	20.36	41,700	20.36
23-Jul-07	21.64	21.65	19.85	20.95	159,800	20.95
20-Jul-07	19.19	25.00	16.83	24.00	356,200	24.00
19-Jul-07	32.40	32.75	31.58	31.80	14,100	31.80
18-Jul-07	31.20	31.99	30.95	31.99	13,600	31.99
17-Jul-07	30.80	30.92	30.75	30.92	4,400	30.92
16-Jul-07	32.00	32.20	31.09	31.10	7,500	31.10
13-Jul-07	31.30	32.00	31.20	31.80	23,400	31.80
12-Jul-07	29.26	29.78	29.19	29.75	15,600	29.75
11-Jul-07	28.30	28.73	28.28	28.59	4,600	28.59
10-Jul-07	28.70	28.75	28.29	28.48	6,900	28.48
9-Jul-07	29.08	29.26	28.99	29.05	8,600	29.05
6-Jul-07	29.20	29.38	29.06	29.31	6,900	29.31
5-Jul-07	29.28	29.28	28.93	29.01	9,800	29.01

3-Jul-07	29.56	29.56	28.81	29.07	12,800	29.07
2-Jul-07	28.74	29.24	28.69	28.89	14,700	28.89

* Close price adjusted for dividends and splits.

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Struggling GPC looking for merger or acquisition

November 28, 2007

Wanted: Private drug developer interested in partnering with struggling biotech specializing in cancer therapies. GPC Biotech essentially posted that message when its CEO announced that he is Read more...

Tags: satraplatin FDA pharmaceuticals drug developer Mergers and Acqusitions cancer therapies GPC Biotech

Troubled GPC cuts staff, looks for M&A deals

November 15, 2007

The failure of GPC Biotech's cancer drug satraplatin in a Read more...

Tags: satraplatin Phase III cancer drug darmstadt germany layoffs GPC Biotech

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November 9, 2007

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Press Releases

PRESS RELEASE: GPC Biotech and Pharmion Announce Results of Overall Survival Analysis from the Satraplatin Pivotal Phase 3 Trial

GPC Biotech and Pharmion Announce Results of Overall Survival Analysis from the Satraplatin Pivotal Phase 3 Trial • Overall survival results do not achieve statistical significance • GPC Biotech Read more...

Tags: molecules Prostate Cancer antibody GPC Biotech satraplatin Phase III FDA drug candidates Phase II cancer drug

GPC shares crater on Phase III cancer failure

October 31, 2007

Germany's GPC Biotech saw its already battered stock price crater this morning after announcing that its experimental prostate cancer drug, satraplatin, failed to help patients live longer in a Read more...

Tags: Cancer Drugs workforce GPC Biotech satraplatin Pharmion Drug Trials cancer drug Prostate Cancer Regulators darmstadt germany

FDA delay forces cutbacks at GPC Biotech

August 23, 2007

Struggling to overcome FDA hurdles for its cancer drug satraplatin, Germany's GPC Biotech says it will slash its staff by 15 Read more...

Tags: darmstadt germany development costs GPC Biotech satraplatin job cuts FDA regulation 1D00C3 Drug Development FDA chief medical officer cancer drug monoclonal antibody

SPOTLIGHT: GPC hit by high R&D costs

August 8, 2007

Germany's GPC Biotech announced wider losses as a result of the expense of developing its prostate cancer therapy Satraplatin. A recent delay in gaining FDA approval of the drug sent GPC shares Read more...

Tags: darmstadt germany FDA approval GPC Biotech satraplatin

Industry exec says FDA approval process too strict

August 1, 2007

Citing the recent decision by GPC Biotech to withdraw its application for satraplatin, Pharmacyclics Read more...

Tags: Phase III FDA pharmaceuticals cancer therapies GPC Biotech satraplatin FDA approval & regulation Biotech company news

GPC yanks FDA application for satraplatin

July 30, 2007

Stymied by FDA regulators, GPC Biotech has pulled its application for satraplatin, an Read more...

Tags: Prostate Cancer Regulators FDA approval GPC Biotech satraplatin experimental therapy Phase III FDA Drug Trials cancer drug

GPC cancer drug voted down by FDA committee

July 25, 2007

An FDA expert committee has dealt a blow to GPC Biotech, concluding unanimously that regulators should wait for survival data before approving its prostate cancer drug Orplatna (satraplatin). The Read more...

Tags: GPC Biotech satraplatin FDA cancer drug spectrum pharmaceuticals Prostate Cancer Regulators

SPOTLIGHT: FDA questions satraplatin

July 23, 2007

Shares of GPC Biotech and Spectrum Pharmaceuticals took a big hit on Friday after the FDA raised questions regarding their cancer drug Read more...

Tags: chemotherapy GPC Biotech satraplatin FDA analysts cancer drug spectrum pharmaceuticals Prostate Cancer

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Press Release: GPC Biotech Announces that Partner Pharmion Submits European Marketing Application for Satraplatin

June 26, 2007

Press Release: GPC Biotech Announces that Partner Pharmion Submits European Marketing Application for Satraplatin

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Tags: Phase III EMEA chemotherapy satraplatin

ALSO NOTED: Natco wins FDA OK; Clinquest gets stake in Enceladus; Pharmion submits MMA; and much more...

June 26, 2007

> The FDA has approved Natco's anti-cancer drug Ondansetron Hydrochloride tablets in multiple strengths. Report

> The Dutch company Clinquest has acquired a stake in Enceladus and has led a syndicate of investors to provide additional funding. Financial details were not disclosed. Release

> GPC Biotech announced that its partner, Pharmion, has ...

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Tags: satraplatin FDA cancer drug EMEA Biogen Idec GPC Biotech

Press Release: GPC Biotech Announces Partnering Agreement for Satraplatin for Japan with Yakult

June 25, 2007

Press Release: GPC Biotech Announces Partnering Agreement for Satraplatin for Japan with Yakult

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Tags: satraplatin Clinical Development milestones upfront payment CEO Japan

ALSO NOTED: GPC inks deal for satraplatin; Acusphere's CFO takes his leave; and much more...

June 25, 2007

> GPC Biotech has signed a licensing agreement with Yakult Honsha for satraplatin in Japan. Release

> Sangamo BioSciences has presents encouraging data from a Phase I trial of its ZFP Therapeutic program. The drug is currently in two Phase II trials for the treatment of diabetic neuropathy.

Release

> AstraZeneca today announced that Symbicort pressurized ...

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Press Release: GPC Biotech Raises Euro 33.6 Million In Private Placement

January 24, 2007

Press Release: GPC Biotech Raises Euro 33.6 Million In Private Placement

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Tags: private placement satraplatin

Pharmion nets cancer therapy in Cabrellis buyout

November 15, 2006

Pharmion has acquired a mid-stage lung cancer therapy--amrubicin--in its deal to buy Cabrellis Pharmaceuticals for $59 million up front. Cabrellis shareholders will also get $12.5 million each for a European and U.S. approval and $10 million each for a European and U.S. approval of a second indication. Pharmion says it will begin a Phase III clinical trial of amrubicin in the latter part of 2007 with drug applications for Europe and the U.S. scheduled for 2009. The drug was approved in ...

Read more...

Tags: Phase III chemotherapy lung cancer satraplatin

Shares surge as satraplatin succeeds in Phase III

September 24, 2006

Shares of Pharmion and GPC Biotech surged after the drug developers announced that volunteers in a Phase III trial of satraplatin for prostate cancer demonstrated a 40 percent reduction in the risk of disease progression. The reduced risks were compared to disease progression among volunteers taking a placebo along with prednisone. Researchers say they will continue to treat volunteers whose cancer has not progressed and track their outcomes. Germany's GPC says it plans to push ahead with ...

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Tags: GPC Biotech satraplatin Phase III milestones spectrum pharmaceuticals Prostate Cancer Regulators

ALSO NOTED: Forest files suit against Caraco; Cephalon R&D chief sees potential; and much more...

July 11, 2006

> Forest Laboratories is suing Caraco Pharmaceutical Laboratories claiming patent infringements on the antidepressant Lexapro. Report

> Cephalon's R&D chief says Wall Street is underestimating the market potential of its experimental cancer therapies. ...

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Tags: cancer therapies GPC Biotech satraplatin New Drug Application Cephalon Cancer Kos Parmaceuticals Forest Lboratories

ALSO NOTED: Zolinza gets priority review; Origen touts transgenics advance; and much more...

June 7, 2006

> The FDA has granted a priority review of Merck's cancer drug Zolinza. The therapy is designed to treat advanced cutaneous T-cell lympyhoma, a cancer of white blood cells. Merck says it expects a decision on Zolinza by October. Report

> Origen Therapeutics says it has designed new techniques for producing genetically altered chickens which can produce drugs. The ...

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Tags: Drug Trials GenMab Merck KgAA GPC Biotech satraplatin

ASCO spawns wave of new cancer data

June 5, 2006

Here's a summary of some of the voluminous cancer data coming from Atlanta's ASCO session. You'll find more in the Clinical Trials Update chart at the bottom of the report.

- here's the summary from *MarketWatch*

ALSO: Biogen Idec and Schering have released new data that demonstrates patients receiving ...

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Tags: satraplatin drug candidates spectrum pharmaceuticals Biogen Idec Bayer Schering lymphoma

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ALSO NOTED: Satraplatin to get expedited survival review; Azilect OK'd for Parkinson's; and much more...

May 17, 2006

> Pharmion and GPC Biotech say that an independent monitoring board will conduct an expedited review of survival data from the Phase III trial of Satraplatin. The companies cautioned against reading too much into the expedited review. Report

> The FDA has approved Teva's Azilect for Parkinson's disease. Teva is also planning a large trial on Azilect's influence on the ...

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Tags: FDA Novartis Teva Parkinson's Valeant Pharmaceuticals GPC Biotech satraplatin

SPOTLIGHT: GPC posts positive satraplatin data

February 26, 2006

Shares of GPC Biotech surged on the news that its lead drug satraplatin was well tolerated in a Phase I trial for advanced solid tumors. The biotech company said on Friday that it had raised $42.8 million to market satraplatin for prostate cancer in the U.S. The therapy is in Phase III trials for prostate cancer as well as other clinical studies for additional oncology indications. Release

Tags: Phase III tumors Prostate Cancer GPC Biotech satraplatin

GPC gains $43.2 million in private placement

February 23, 2006

Germany's GPC Biotherapeutics, which has research facilities in Waltham, MA, has raised $43.2 million in a private placement of shares to two investment firms. GPC has been attracting attention with the recent announcement of a fully enrolled Phase III trial for satraplatin, a second-line chemotherapy being studied for prostate cancer. The FDA has granted fast track status to satraplatin.

- read this report from *Mass High Tech*

Tags: Phase III FDA private placement Prostate Cancer darmstadt germany chemotherapy satraplatin

Spectrum outlines $40M in milestones

January 22, 2006

Spectrum Pharmaceuticals says it will be in a position to garner up to $40 million more in milestone payments after its drug development partner GPC Biotech recently licensed the marketing rights of their cancer drug satraplatin to Pharmion for Europe and several other countries. Those payments

are in addition to the $18 million in milestones outlined in an earlier deal between GPC and Spectrum. GPC says it expects to file an NDA for satraplatin by the end of this year, with an ...

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Tags: Drug Development sales and marketing EMEA Europe milestones spectrum pharmaceuticals Cancer Drugs GPC Biotech satraplatin

Pharmion signs $270M licensing deal for GPC's satraplatin

December 19, 2005

US drug maker Pharmion has agreed to pay $37.1 million up front and a potential total of up to $270 million in milestones for some of the marketing rights to GPC Biotech's cancer drug satraplatin. Pharmion gains the rights to Europe, Turkey, the Middle East, Australia and New Zealand while Germany's GPC keeps North America and all other markets. GPC will also earn royalties from any sales. Satraplatin is in late-stage trials for prostate cancer and is estimated to be worth about $500 ...

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Press Release: GPC Biotech Announces that Partner Pharmion Submits European Marketing Application for Satraplatin

June 26, 2007

Press Release: GPC Biotech Announces that Partner Pharmion Submits European Marketing Application for Satraplatin

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Tags: Phase III EMEA chemotherapy satraplatin

ALSO NOTED: Natco wins FDA OK; Clinquest gets stake in Enceladus; Pharmion submits MMA; and much more...

June 26, 2007

> The FDA has approved Natco's anti-cancer drug Ondansetron Hydrochloride tablets in multiple strengths. Report

> The Dutch company Clinquest has acquired a stake in Enceladus and has led a syndicate of investors to provide additional funding. Financial details were not disclosed. Release

> GPC Biotech announced that its partner, Pharmion, has ...

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Tags: satraplatin FDA cancer drug EMEA Biogen Idec GPC Biotech

Press Release: GPC Biotech Announces Partnering Agreement for Satraplatin for Japan with Yakult

June 25, 2007

Press Release: GPC Biotech Announces Partnering Agreement for Satraplatin for Japan with Yakult

Read more...

Tags: satraplatin Clinical Development milestones upfront payment CEO Japan

ALSO NOTED: GPC inks deal for satraplatin; Acusphere's CFO takes his leave; and much more...

June 25, 2007

> GPC Biotech has signed a licensing agreement with Yakult Honsha for satraplatin in Japan. Release

> Sangamo BioSciences has presents encouraging data from a Phase I trial of its ZFP Therapeutic program. The drug is currently in two Phase II trials for the treatment of diabetic neuropathy.

Release

> AstraZeneca today announced that Symbicort pressurized ...

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Press Release: GPC Biotech Raises Euro 33.6 Million In Private Placement

January 24, 2007

Press Release: GPC Biotech Raises Euro 33.6 Million In Private Placement

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Tags: private placement satraplatin

Pharmion nets cancer therapy in Cabrellis buyout

November 15, 2006

Pharmion has acquired a mid-stage lung cancer therapy--amrubicin--in its deal to buy Cabrellis Pharmaceuticals for $59 million up front. Cabrellis shareholders will also get $12.5 million each for a European and U.S. approval and $10 million each for a European and U.S. approval of a second indication. Pharmion says it will begin a Phase III clinical trial of amrubicin in the latter part of 2007 with drug applications for Europe and the U.S. scheduled for 2009. The drug was approved in ...

Read more...

Tags: Phase III chemotherapy lung cancer satraplatin

Shares surge as satraplatin succeeds in Phase III

September 24, 2006

Shares of Pharmion and GPC Biotech surged after the drug developers announced that volunteers in a Phase III trial of satraplatin for prostate cancer demonstrated a 40 percent reduction in the risk of disease progression. The reduced risks were compared to disease progression among volunteers taking a placebo along with prednisone. Researchers say they will continue to treat volunteers whose cancer has not progressed and track their outcomes. Germany's GPC says it plans to push ahead with ...

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Tags: GPC Biotech satraplatin Phase III milestones spectrum pharmaceuticals Prostate Cancer Regulators

ALSO NOTED: Forest files suit against Caraco; Cephalon R&D chief sees potential; and much more...

July 11, 2006

> Forest Laboratories is suing Caraco Pharmaceutical Laboratories claiming patent infringements on the antidepressant Lexapro. Report

> Cephalon's R&D chief says Wall Street is underestimating the market potential of its experimental cancer therapies. ...

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Tags: cancer therapies GPC Biotech satraplatin New Drug Application Cephalon Cancer Kos Parmaceuticals Forest Lboratories

ALSO NOTED: Zolinza gets priority review; Origen touts transgenics advance; and much more...

June 7, 2006

> The FDA has granted a priority review of Merck's cancer drug Zolinza. The therapy is designed to treat advanced cutaneous T-cell lympyhoma, a cancer of white blood cells. Merck says it expects a decision on Zolinza by October. Report

> Origen Therapeutics says it has designed new techniques for producing genetically altered chickens which can produce drugs. The ...

Read more...

Tags: Drug Trials GenMab Merck KgAA GPC Biotech satraplatin

ASCO spawns wave of new cancer data

June 5, 2006

Here's a summary of some of the voluminous cancer data coming from Atlanta's ASCO session. You'll find more in the Clinical Trials Update chart at the bottom of the report.

- here's the summary from *MarketWatch*

ALSO: Biogen Idec and Schering have released new data that demonstrates patients receiving ...

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Tags: satraplatin drug candidates spectrum pharmaceuticals Biogen Idec Bayer Schering lymphoma

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ALSO NOTED: Satraplatin to get expedited survival review; Azilect OK'd for Parkinson's; and much more...

May 17, 2006

> Pharmion and GPC Biotech say that an independent monitoring board will conduct an expedited review of survival data from the Phase III trial of Satraplatin. The companies cautioned against reading too much into the expedited review. Report

> The FDA has approved Teva's Azilect for Parkinson's disease. Teva is also planning a large trial on Azilect's influence on the ...

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Tags: FDA Novartis Teva Parkinson's Valeant Pharmaceuticals GPC Biotech satraplatin

SPOTLIGHT: GPC posts positive satraplatin data

February 26, 2006

Shares of GPC Biotech surged on the news that its lead drug satraplatin was well tolerated in a Phase I trial for advanced solid tumors. The biotech company said on Friday that it had raised $42.8 million to market satraplatin for prostate cancer in the U.S. The therapy is in Phase III trials for prostate cancer as well as other clinical studies for additional oncology indications. Release

Tags: Phase III tumors Prostate Cancer GPC Biotech satraplatin

GPC gains $43.2 million in private placement

February 23, 2006

Germany's GPC Biotherapeutics, which has research facilities in Waltham, MA, has raised $43.2 million in a private placement of shares to two investment firms. GPC has been attracting attention with the recent announcement of a fully enrolled Phase III trial for satraplatin, a second-line chemotherapy being studied for prostate cancer. The FDA has granted fast track status to satraplatin.

- read this report from *Mass High Tech*

Tags: Phase III FDA private placement Prostate Cancer darmstadt germany chemotherapy satraplatin

Spectrum outlines $40M in milestones

January 22, 2006

Spectrum Pharmaceuticals says it will be in a position to garner up to $40 million more in milestone payments after its drug development partner GPC Biotech recently licensed the marketing rights of their cancer drug satraplatin to Pharmion for Europe and several other countries. Those payments

are in addition to the $18 million in milestones outlined in an earlier deal between GPC and Spectrum. GPC says it expects to file an NDA for satraplatin by the end of this year, with an ...

Read more...

Tags: Drug Development sales and marketing EMEA Europe milestones spectrum pharmaceuticals Cancer Drugs GPC Biotech satraplatin

Pharmion signs $270M licensing deal for GPC's satraplatin

December 19, 2005

US drug maker Pharmion has agreed to pay $37.1 million up front and a potential total of up to $270 million in milestones for some of the marketing rights to GPC Biotech's cancer drug satraplatin. Pharmion gains the rights to Europe, Turkey, the Middle East, Australia and New Zealand while Germany's GPC keeps North America and all other markets. GPC will also earn royalties from any sales. Satraplatin is in late-stage trials for prostate cancer and is estimated to be worth about $500 ...

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YE2006 – Press Conference and Analyst Meeting

The spoken word shall prevail

Speaker: Dr. Claudia Gutjahr-Löser, Head of Corporate Communication

It is my pleasure to welcome all of you to our annual conference. My name is Claudia Gutjahr-Löser and I am the Head of Corporate Communications at MorphoSys. I would like to thank you for your interest and participation at our conference today. With me are Dr. Simon Moroney, our CEO, and Dave Lemus, our CFO.

Slide 2: Safe Harbour

Before we start, we want to remind you that during this conference we will present and discuss certain forward-looking statements concerning the development of MorphoSys' core technologies, the progress of its current research programs and the initiation of additional programs. Should actual conditions differ from the company's assumptions actual results and actions may differ from those anticipated. You are therefore cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date hereof.

Slide 3: Agenda

Today we will present the company's annual results for 2006. We have planned approx. one hour for the presentation. Simon will start with a review of 2006. Subsequently, Dave will give you an overview about the financial results of 2006, and present the guidance for 2007. Before we start with the questions and answers session, Simon will speak about the outlook for 2007 and beyond. At the end of our presentations, we will take questions that this conference audience and those participants listening-in on the phone may have. For the participants of the conference call, you can view the slides on our corporate website.

I would like now to hand over to Simon Moroney, our CEO, who will start with his summary of the year 2006.

Speaker: Dr. Simon Moroney, CEO of MorphoSys AG

Thank you, Claudia. I'd like to add my welcome to this, our year-end 2006 press and analyst conference.

Slide 4: Group Milestones 2006

I want to start with an overview of MorphoSys's achievements. We exceeded our financial targets for the year, increasing revenue by 58% over 2005 to € 53 million. We strengthened our core partnered therapeutic antibody discovery business by adding three new partners and expanding three existing alliances. Overall, our pipeline has advanced considerably: a second HuCAL antibody entered clinical trials when Roche took our anti-amyloid-ß antibody into the clinic for the treatment of Alzheimer's disease. GPC reported data from their ongoing phase I trial of the HuCAL antibody 1D09C3. Our partnered pipeline reached 43 compounds and we advanced our proprietary therapeutic antibody programs MOR103 and MOR202 according to plan. Regarding our technology, we reported a very important advance with the release of our new RapMAT technology for antibody optimization. And last but not least, we transformed our research antibodies segment from a fledgling business unit to a top 20 player worldwide via the acquisition of Serotec, and are leading the technological transformation of this market.

All in all, we had an outstanding year. Most importantly, the progress we made puts the company in a strong position to continue its successful development in the future.

Slide 5: Agenda

This was all achieved against the backdrop of some extraordinary developments in our industry. The demand for antibody technologies in the pharmaceutical industry is accelerating. The year 2006 could be remembered as the year the pharmaceutical industry became convinced of the importance of therapeutic antibodies as a class of drugs.

Slide 6: Therapeutic Antibodies: A Market Hotter Than Ever

As shown on this slide number 6, 2006 witnessed seven acquisitions of antibody-based biotech companies by big pharma. This is the proof, if it were needed, that the industry is convinced by antibodies as a class of drugs. Other highlights in the sector were the return to the market of Tysabri, Biogen Idec and Elan's innovative antibody-based therapy for multiple sclerosis, and the enormously successful launch of Lucentis, Genentech's Fab fragment for wet AMD. Together with the ongoing success of many of the existing marketed therapeutic antibodies, the new launches helped total turnover for the year to exceed US$ 15 billion.

These events all underscore the fact that MorphoSys is active in a highly attractive segment of the pharmaceutical industry. Furthermore, we expect interest to continue to be high in the years ahead as more and more pharmaceutical and biotech companies look to develop antibody-based drugs.

The significance for MorphoSys of these industry developments comes on several levels. First, we find ourselves with less direct competition than several years ago, due to the acquisition of key competitors such as Abgenix and Cambridge Antibody Technology. MorphoSys's position as the leading independent recombinant antibody company is now stronger than ever before. Second, the success of antibodies as drugs has catalyzed the development of a new segment of the biotech industry, namely the scaffold field, in which antibody-like recombinant proteins of different types are being developed as drugs. This creates a new competitive challenge for us,

and highlights the need for ongoing technology development in order for us to maintain our current position as the partner of choice for companies seeking to develop protein based therapeutics. Third, interest in therapeutic antibodies in the pharmaceutical industry continues to be strong despite the tragic events associated with the phase 1 clinical study of TeGenero's anti CD28 antibody in March last year. This unfortunate occurrence did serve to highlight the care that is required during the pre-clinical development of antibodies, particularly those that work by activating components of the immune system.

Slide 7: Recent Deal Flow – Existing Partnerships

Looking at our deal flow, 2006 was, once again, a banner year for MorphoSys. We were happy to be able to expand three of our most important relationships.

Our biggest partnership is with Novartis. In June we signed an early amendment which will take our collaboration out to 2011, and which significantly increases the number of programs being pursued. This is a very important alliance for us, but also for Novartis, as evidenced by the fact that 1/3 of their preclinical biologics pipeline comprises HuCAL antibodies.

We were also able to extend our collaboration with Pfizer. As with the Novartis deal, this agreement still had some time to run, but, again as with Novartis, Pfizer has been so pleased with the progress of the 5 therapeutic programs running under the original deal that they elected to extend early. This agreement will now run to the end of 2011. As a result of the expansion, the potential value for MorphoSys in research funding and potential developmental milestone payments increased to more than US$ 100 million, not including royalties. It is worth noting that Pfizer had relationships with both Abgenix and CAT, and it is highly likely that the fact that those two competitors were both acquired smoothed the way for our expansion with Pfizer.

Hoffmann-La Roche added two new cancer programs to our relationship, on the back of taking the antibody we made for them for Alzheimer's disease into the clinic.

Another development involving two of our long-standing partners was the merger of Bayer and Schering during the year. At the time, we announced that this would result in a consolidation of the two agreements. As a first step, at the end of last year Bayer exercised an option to terminate our agreement, with the intention of proceeding under the ongoing Schering agreement, which was extended until the end of 2007. We continue to work with Bayer-Schering on how best to structure our collaboration going forward.

Slide 8: Deal Flow 2006 – Three New Partnerships

In addition, we signed up three new partners. Daiichi Sankyo and Schering-Plough each secured up to 5-year licenses to apply the HuCAL technology internally, and became respectively our 11th and 12th partnerships with top 20 pharma. We also added OncoMed to our roster of partners. OncoMed is a Genentech spin-out pursuing target discovery with so-called tumor stem cells. OncoMed's approach is unique, and is based on the concept that tumors derive from specialized precursor or "stem" cells. OncoMed received a license to use the HuCAL technology in their discovery research for two years.

Partnered therapeutic antibody discovery forms the core of our business, providing approximately 2/3 of our revenue. But even more importantly, it represents substantial future value for MorphoSys, since we will earn royalties on every HuCAL-derived drug that comes to market. We therefore place particular emphasis on the progress of our partnered pipeline and 2006 was an outstanding year in this regard.

Slide 9: Partnered HuCAL Therapeutic Antibody Pipeline – Growth and Maturing

As of today, the total number of active, partnered therapeutic antibody programs is 43, an increase of almost 50% over the number at the beginning of last year. The maturity of the pipeline also advanced, with currently 2 programs in the clinic, 14 in pre-clinical development, and 27 in research. I'll come back to the importance of the partnered pipeline for our future at the end of the presentation.

Slide 10: Roche's HuCAL-based Alzheimer Antibody

There are now two HuCAL antibodies in clinical trials. In May of last year, Roche initiated a phase 1 clinical trial with the anti-amyloid-ß antibody that we developed for them for the treatment of Alzheimer's disease. Roche is currently running two European phase 1 studies. Both trials are randomized, double-blinded studies in patients; the first trial is a multiple, ascending dose study, while the second is using a single dose. The trials are now progressing at centers in Denmark, Holland, Sweden and the United Kingdom. As these two trials are being conducted in patients, as opposed to healthy volunteers, it may be possible to observe signs of clinical efficacy.

Slide 11: First HuCAL Antibody in Man – GPC Biotech's 1D09C3

Roche's Alzheimer's program became the second HuCAL antibody to enter human clinical trials, after GPC's 1D09C3 for cancer. During the year, GPC announced preliminary clinical data from the ongoing phase I trial in relapsed and refractory B-cell lymphomas involving 3 European sites. The antibody appears to be well-tolerated and hints of anti-tumor activity were observed. GPC expects to complete the phase I trial in the middle of this year and move into a phase 2 trial thereafter. The drug has been granted orphan status by the European Commission in chronic lymphocytic leukaemia, multiple myeloma and Hodgkin's lymphoma.

Slide 12: Agenda

I'd like to turn now to our proprietary drug development programs MOR103 and MOR202, which we advanced during 2006 according to schedule.

Slide 13: "The $100 Million IND" – Biotech's Increased Leverage with Big Pharma

Our future plans for both of our proprietary programs are being developed with one eye on deals being done in the industry. We have all witnessed the extraordinary sums being paid by big pharma and biotech for interesting drug candidates, even in early stages of development. The industry publication IN VIVO recently published an article entitled "The $100 Million IND". The gist of the article was that recent deals prove that pharma is now prepared to pay this amount for compounds at this stage of development. These developments are of course to the advantage of the biotech industry and validate MorphoSys's strategy of channeling investment into programs that we have initiated ourselves.

For the last 12 months, we have been fully focused on advancing the development of MOR103 and MOR202 according to plan, and have not engaged in any discussions with potential future partners. While we will continue to work on both programs, once the data packages have advanced, we will make these programs a subject of our regular meetings with pharma and biotech companies. In other words, we will consider offers from partners for the further development of the two compounds. While we feel under no pressure to secure a partner for

either program, we want to remain flexible – our goal is to maximize our return on investment for each program.

Slide 14: MOR103 on Track to H2 2007 IND

Our most advanced program is MOR103 for the treatment of rheumatoid arthritis.

There is still a high unmet medical need in RA treatment, since fewer than 25% of patients are currently adequately treated. Non-responders and long-term safety concerns associated with the existing anti-TNF therapies provide strong incentives for new treatment options, especially for new mechanisms of action.

During 2006, we have continued to investigate the lead antibody for this program, and have become even more convinced that we have a potential drug. These studies have given us the confidence to embark on the critical manufacturing and process development part of the program.

In 2006, we signed a license and manufacturing agreement with Crucell and its technology partner DSM Biologics for production of clinical grade material using the well established and fully human PER.C6 cell line. This brings together our fully human antibody with production capabilities in a fully human host. Manufacturing human antibodies in such a manner offers several potential advantages over alternative production methods, especially when targeting chronic diseases such as rheumatoid arthritis.

Production is proceeding according to schedule, as are our ongoing pre-clinical experiments. We remain on track to file an IND for this program in the second half of this year.

Slide 15: Proprietary Cancer Program: MOR202

Our second proprietary program is MOR202, the anti-CD38 approach to the treatment of multiple myeloma. Here, we reached our objective of selecting a formal pre-clinical development candidate by year-end. The candidate we chose shows good efficacy in *in vitro* and *in vivo* models, and is well produced and behaved. In 2007, we will continue pre-clinical development of this compound.

Slide 16: Agenda

I want to turn now to technology. The success of all of our therapeutic antibody programs, both partnered and proprietary, hinges on the quality of the antibodies that can be made with the HuCAL technology.

Key parameters for an antibody drug include not only the obvious ones such as target affinity and specificity but also disease-modifying activity, immunogenicity, solubility, stability, production characteristics and others. One of the great advantages of the HuCAL technology is its ability to deliver high quality antibodies quickly. Precisely these features are at a premium in our industry, and we have long recognized the need to do even better here.

Slide 17: Technology Development: RapMAT Increases Affinity & Diversity

This is the logic behind RapMAT, a HuCAL-related technology for making better antibodies even faster.

RapMAT is a new process that exploits the modular design of the HuCAL library to optimize antibodies even faster than is currently possible. Based on our experience to date, the main advantages of this process are two-fold. First, substantial time savings can be made in the

optimization of lead antibodies - RapMAT takes up to 30 % off the time of the standard selection process, that may normally last 6-12 months.

Slide 18: Technology Development: RapMAT Increases Affinity & Diversity (II)

As you can see from the chart on slide 18, a typical improvement in affinity may be by a factor of 10- to 40-fold. Second, the process results in a greater diversity of lead candidates. This is especially important in drug development since the greater the diversity of the leads generated, the higher the probability that one having drug-like qualities will be obtained.

RapMAT is now integrated in our drug discovery programs, and we expect it to make our drug discovery even more efficient.

We continue to invest in developing the HuCAL technology. The goal is very simple: to make effective and safe therapeutic antibody candidates faster than before. We will update you on new developments as they come on line.

Slide 19: Agenda

I would like to turn now to the second pillar of our business, namely our research antibodies segment AbD Serotec. This unit combines our custom HuCAL antibody generation service with our two acquisitions in the research antibody space, Biogenesis and Serotec. This segment has come a long way in a short time: having commenced operations less than 4 years ago, we are now one of the world's top 20 suppliers of research antibodies. We intend to improve this position still further.

Slide 20: Global MorphoSys Group Sites

The year was very much focused on consolidation and integration of the component pieces of this business. The majority of our staff in this unit is now located in a brand new facility in Kidlington, just north of Oxford in England. This consolidates the former Biogenesis operation from Poole on the south coast, with the former Serotec and Oxford Biotechnology operations outside Oxford. Altogether we have about 80 staff on this site. In addition to consolidation of the sites in England, we moved our Raleigh, North Carolina sales office to new premises during the year. Operations for the unit, including antibody generation and manufacturing, are in Oxford and at MorphoSys headquarters in Munich, and we have sales staff at these sites as well as in Raleigh and New Hampshire in the US, Düsseldorf in Germany and Hamar in Norway.

Slide 21: AbD Serotec – Highlights 2006

We are delighted that despite the enormous upheaval associated with integrating three organizations, consolidating several teams and establishing two new premises, the AbD Serotec team was able to achieve the ambitious revenue target we set for them at the beginning of the year.

In addition, the unit developed a number of important relationships during 2006. Just to mention a few, we entered:

- A marketing alliance with Chemicon,
- Technology and marketing alliances with Thermo Fisher Group and Chimera Biotec,
- A discovery collaboration with the Kazusa DNA Research Institute in Japan,

- And a sole source agreement with the US Army Medical Research Institute for Infectious Diseases – or USAMRIID for short,

Over the last couple of months we've also entered research agreements with The Burnham Institute and with a leading Japanese research institute, both of which were sourced by the AbD Serotec unit. These are of particular significance for the company as a whole, and I'll return to this topic in the outlook section of the presentation.

The loss that AbD Serotec recorded arose primarily because of one-off, acquisition-related charges, and we are confident that, in addition to solid top-line growth, AbD Serotec will record a profit this year.

Slide 22: Agenda

That concludes the review of the year. I now want to hand over to Dave Lemus for his presentation of the financial results.

Speaker: Dave Lemus, CFO of MorphoSys AG

Slide 22: Agenda

Thanks, Simon. I'd now like to continue with the financial review for the fiscal year 2006. In opening, I'm pleased to say, that 2006 was an excellent year - not only operationally, but also financially speaking.

Slide 22: Financial Review: Highlights 2006

On this first chart, you can see some of the financial highlights of the year.

Revenues for the MorphoSys Group increased by 58 % to € 53 million, leading to a net profit of € 6.0 million. Removing Serotec from the picture, revenues grew organically by a solid 22 %.

In January 2006, we acquired the Serotec Group to further strengthen the Research Antibodies segment. In 2006, Serotec contributed € 12.3 million or 23 % of total Group revenues.

Our cash position increased to € 66 million, in part through a successful private placement in March 2006 as well as from a strong positive cash flow from operations of € 16.3 million.

Last but not least we were recognized in annual STEP Award in the category "Finance", highlighting achievements in that area of the company during the year.

I'd now like to go into more detail of our 2006 financial results.

Slide 23: Revenue Breakdown 2006

Let's start with revenues. The next chart shows where our revenue growth has arisen.

Revenues of the MorphoSys Group for the full year 2006 increased by 58 % to € 53 million, which slightly exceeded our guidance. Group revenues, measured in constant currency, would have been about € 1 million lower than actual, mainly due to the weaker dollar.

Revenues from the therapeutic antibody segment increased by € 5.6 million to € 34.7 million. As we had no acquisitions on the therapeutic side of our business, the therapeutic antibodies segment grew organically by around 19 %. Performance-based payments from partners increased to € 7.5 million, providing 22 % of the segment revenues, an increase of 9 % in comparison to 2005. The payments in 2006 include the clinical phase 1 milestone from our partner Roche.

While the Research Antibody Segment contributed in 2005 13 % to total Company revenues, in 2006 we saw the segments contribution increase to 35 % or € 18.3 million – mainly as a result of the acquisition of the Serotec Group. As we reported earlier, the Serotec business is now fully integrated with MorphoSys's Research Antibodies Segment, named AbD. The organic revenue growth of the segment – that is, if you remove the effect of Serotec from our 2006 revenues – would have resulted in organic growth of approximately 40%.

In summary, organic revenue growth for both segments in total was 22 %, which is in line with our goal to experience annual organic growth in excess of 15% each year.

Slide 25: Revenues (Group): Geographic Split

If we take a look at where sales geographically arose, 62 % of MorphoSys's commercial revenues were generated with biotechnology and pharmaceutical companies as well as AbD customers located in Europe and Asia, compared with 56 % last year. This reflects a trend we

have seen now for the last couple of years, where our cooperation partners in Europe and in particular Asia will continue to be very important to us. Looking at the two segments sales in isolation and how they geographically split, revenue geographically generally mirrors the total Company numbers.

Slide 26: Revenues Therapeutic Antibodies Segment: Performance-Based Payments

I think it is important to highlight the increasing amounts of performance-based payments. With a partnered pipeline of currently 43 antibody programs ongoing, this is another big picture trend -- namely we will see that performance-based payments will continue to be a larger part of our revenue streams. As you can see from the chart, they have increased in absolute terms over the last couple of years. We anticipate this trend to continue in 2007, also in percentage terms, which is good news to MorphoSys, as these payments represent pure profit and upside for the Company. For 2007, we expect 1 – 3 INDs, and 2008 is expected to generate even more IND filings, which again should help our result.

Within the scope of MorphoSys's larger antibody partnerships, license payments and research funding still represent the majority of revenues. The good news here is that many cooperations were extended in the last couple of years, making several of these revenue streams committed over the next several years. That in turn allows us a higher planning certainty as it relates to our thoughts ahead. Driving that point home, at the beginning of 2007, approximately two thirds of the revenues of the Therapeutic Antibodies segment were already committed and secured.

Slide 27: Operating Expenses (Group)

Let's move to operating expenses.

Total operating expenses increased by 72 % to € 46.9 million. The total increase in operating expenses of € 19.6 million was mainly due to the inclusion of the Serotec Group in the consolidated accounts with an impact of € 13.8 million. Higher personnel-related costs in conjunction with new collaborations and increased expenses for proprietary product development also impacted expenses.

Comparing this against guidance, operating expenses were at the lower end of the range, identical to what we confirmed during our Q3 2006 conference call.

Moving on to Costs of Goods Sold, or COGS. As you all recall, COGS in our Company only arise in the Research Antibodies segment. For the year 2006, total COGS rose to € 8.0 million compared to € 2.5 million in the year 2005, which resulted mainly from the € 5.5 million inclusion of Serotec COGS in the consolidated Group accounts.

Costs for research and development arise mainly in the therapeutic antibody unit. R&D costs increased by 25 % to € 17.5 million. This increase was mainly the result of expenses for product and technology development amounting to approximately € 3.0 million.

Sales, general and administrative expenses amounted to € 21.4 million, an increase of 98 % compared to the previous year. The increase is mainly derived from the inclusion of the Serotec Group in the amount of € 8.3 million. Also driving higher S, G&A costs were increased personnel costs at the MorphoSys AG headquarter in Munich, and one-off integration costs associated with acquired companies.

Stock-based compensation in the amount of € 1.2 million for the year 2006 was recorded as a non-cash charge, and is embedded in cost of goods sold, S,G&A expenses as well as R&D expenses. Stock-based compensation changed little in comparison to last year.

Slide 28: Results by Segment

Let's look at the result by segment. On the therapeutic side, revenues amounted to € 34.7 million, compared our guidance estimate of € 34 million, influenced by higher levels of performance-based payments and by new and expanded collaborations. Operating expenses of the Therapeutic Antibodies segment increased by 27 % to € 18.1 million, mainly driven by expenses for proprietary product and technology development in the amount of € 3 million. The resulting operating segment result was a very strong € 16.6 million.

Moving to the Research segment, total sales were € 18.3 million, and total expenses of € 21.7 million, mainly impacted by strong organic growth and the Serotec acquisition. The result - a loss of € 3.4 million - was a bit under our expectations and guidance, mainly due to higher and earlier than expected restructuring costs. Cash flow in the unit however, looks a bit better.

Slide 29: AbD Segment: Cash Flow & Restructuring Cost

In order to get to cash flow for the unit, in this next chart, we removed amortization approximately € 1.0 million, depreciation of € 0.9 million and stock-based compensation of € 0.2 million, and then subtracted Capex of € 1.9 million. The result is a reasonably good proxy for cash usage or generation of the unit. As you can see, once you remove these non cash items, cash usage of the unit was closer to € 3.2 million. One-off restructuring costs in the amount of € 1.7 million are also included in the operating result. All said and done, we expect now an improvement looking ahead, and for 2007, we expect the segment to be both cash positive, and have an operational income. More on that in the guidance section.

Slide 30: Sites Consolidation & Streamlining of Group Corporate Structure

In our last slide, we discussed restructuring costs. On that note, let me just add some words to our corporate structure and the successful conclusion of the integration exercise. Shortly after the acquisition of the Serotec Group in January 2006 we decided to consolidate some of our sites. Presently we have our premises for this unit in Munich, Germany, in Oxford in the UK and in Raleigh in the USA. We also decided to keep small sales offices in Dusseldorf, Germany, in New Hampshire in the US, and in Norway.

In the UK, several former Biogenesis employees were moved to Oxford, and we have decided to close down the site in Poole, which was completed by the end of 2006. We are presently renting the site over the next two years, have divested the equipment to a buyer. At the end of this period, we expect to find a buyer for the building and the land.

Our US activities are now concentrated in the Research Triangle in Raleigh, North Carolina. We have a sales force sitting there, comprising approximately 20 people, which serve the US market. Additionally, we keep a smaller satellite sales office in New Hampshire.

Slide 31: New Group Corporate Structure

This next chart represents our corporate legal structure as per January 2007. It is the result of a streamlining of the corporate structure undertaken at the end of last year. On the left hand, this is our former US subsidiary in Charlotte, MorphoSys USA Inc., which substantially ceased its operations a few years back. The Poole Real Estate Ltd. is the former Biogenesis Ltd., which

possesses the real estate holdings of the ex-Biogenesis site, and is the current landlord of that site. MorphoSys IP GmbH was founded a couple of years ago, and holds a substantial portion of the IP rights of MorphoSys AG.

MorphoSys UK Ltd. was formerly known as Serotec Ltd., and has been renamed recently. It has two affiliates, MorphoSys US Inc., which is the former Serotec Inc., and MorphoSys AbD GmbH, which is the former Serotec GmbH in Dusseldorf here in Germany. Oxford Biotechnology Ltd. and the Oxford Biomarketing Ltd. are currently in liquidation.

Slide 32: Non-operating Items and Taxes (Group)

Moving back to the financial review, I would like to continue with non-operating items. Profit from Operations remained almost unchanged at € 6.2 million compared to 2005, and is very close to our guidance given that we would be on the upper range of € 6 million.

Earnings before interest, taxes, depreciation and amortization – or EBITDA – amounted to € 10.3 million compared to € 8.6 million in the previous year.

Beneath the non-operating section is income tax; we had a benefit from income taxes of € 0.7 million. This has resulted from movements from our deferred tax liabilities and assets, but was also heavily impacted by the establishment of a deferred tax asset of approximately € 1.2 million relating to our tax loss carry-forwards for 2007.

MorphoSys achieved a net profit of € 6.0 million under IFRS. The resulting diluted net income per share for the full year 2006 amounted to 93 Cent per share, compared to an EPS of 83 Cent per share last year.

Slide 33: Capital Expenditure by Segments

In the fiscal year 2006, MorphoSys's investment in property, plant and equipment as well as in intangibles amounted to € 4.0 million resulting in an increase of € 3.3 million compared to the same period of the prior year. Consolidating the Group's UK activities into our new UK headquarters in Oxford contributed € 1.2 million to the same. We believe the UK capex requirements looking ahead, are substantially fulfilled by this investment.

Depreciation of property, plant and equipment for 2006 accounted for € 1.5 million, compared to € 0.9 million in 2005. The increase was mainly related to the Serotec acquisition.

Let's now move to the Balance Sheet.

Slide 34: Consolidated Balance Sheet - Assets (Group)

If you look at the balance sheet, you can see that the Company's current assets increased by about € 18 million to € 76.1 million, mainly as a result of the capital increase successfully completed in March 2006. The cash position increased to € 66 million at the end of the year. Looking at the non-current assets, you can see these have more than doubled to € 51.7 million, which mainly is the result of consolidating Serotec's hard and soft assets, especially goodwill, into our balance sheet.

Let's move to the next slide, liabilities.

Slide 35: Balance Sheet – Liabilities (Group)

During the year 2006, current liabilities increased by approximately € 7 million to € 18.3 million. This change is primarily a result of the inclusion of the Serotec entities into the consolidated

financial statements. The growth in non-current liabilities was significantly impacted by the rise of non-current deferred revenues by € 2.5 million due to payments arising from new contracts signed in 2005 and 2006, and a buildup in deferred tax liabilities resulting from the Serotec Purchase Price Accounting exercise.

Slide 36: Share Issuance 2006

Looking at changes in share capital during the year, two capital increases were carried out. As part of the acquisition of the Serotec Group in January 2006, one-third of the purchase price was paid by means of a capital increase against contribution in kind. The 208,560 new shares from the capital increase or 3.5 % of the share capital went to the former owners of the Serotec Group and are subject to a graded holding period.

In March 2006, MorphoSys successfully placed around 6.5 % of our outstanding share capital in a private placement to international institutional investors, resulting in gross proceeds of approximately 17.1 million € to the Company.

Beyond that, roughly 97,000 shares were issued as a result of employee convertible bond and options exercises.

At year-end 2006, the total number of shares issued was roughly 6.7 million shares.

Slide 37: Shareholder Structure

Looking at our shareholder structure, presently our biggest shareholder is Novartis Pharma AG, who owns about 7 %, followed by AstraZeneca with approximately 6 %. The free float, according to the definition of Deutsche Börse, amounted to roughly 87 %, and includes approx. 3 % of shareholdings by the Management and Supervisory Boards.

It is may be worthwhile mentioning, that in the course of 2006, more than 200 investor meetings were held in 10 countries and institutional shareholdings roughly doubled over the prior year, and we currently estimate these shareholdings at around 40 % of total share capital.

Slide 38: Employees

At the end of the year 2006, the MorphoSys Group employed 279 employees, compared to 172 employees at year-end 2005. Of the 279 employees, 158 worked in the Therapeutic Antibodies segment, and 121 in the AbD segment.

Of total employees, 183 worked in Germany, 78 in the UK, and 18 in the US.

Slide 39: Agenda

That concludes my review for the year 2006. I'd like to continue with the outlook for 2007.

Slide 40: Financial Outlook 2007

Let's move to the financial outlook for 2007. We estimate revenues for the full year 2007 to range between € 60 and 65 million.

We anticipate that approx. 2/3 of the revenues will be generated by the Therapeutic Antibodies Segment. Of this amount, we expect performance-based payments to make up a total of approximately € 10 million.

We expect that the Research Antibodies segment will contribute approximately one third of total revenues, including Serotec.

There are a number of assumptions which have been put into the expense line for 2007. First and foremost, included in our assumptions is approximately € 5 million worth of investment expense in the proprietary products and roughly € 1 million in proprietary technology advancement.

Looking at guidance by segment, in the therapeutic unit, we expect the unit to be profitable as last year. As it relates to the AbD segment, we expect in 2006 an operational profit somewhere between 5-10% of sales.

Slide 41: Agenda

That concludes the financial analysis of 2006 and the guidance for 2007, and I would now like to hand back now to Simon for the goals for 2007.

Thank you very much for your attention.

Speaker: Dr. Simon Moroney, CEO of MorphoSys AG

Thanks, Dave.

To conclude the presentation, I'd like to talk about how we intend to use our current strength for future growth and finish by presenting our goals for 2007.

Looking to our future, I want to make two key points about our pipeline and our strategy.

Slide 42: Partnerships Hit Critical Mass

The first point is that our partnered therapeutic discovery business has now hit critical mass.

The six deals that we signed during 2006, together with the other running partnerships, will result in sufficient royalties from HuCAL drugs on the market to secure our long-term future. Our updated projections suggest that the currently active partnerships should result in at least 9 HuCAL antibody drugs coming to market.

How do we reach this conclusion? It is based on the number of programs ongoing or pending within our current partnerships and the probability that these programs will result in marketed drugs. The next two slides take you through this calculation.

Slide 43: Partnered Programs: Today & Tomorrow

We currently have 43 active programs. We project at least 7 new starts in 2007, meaning that number should increase to 50 by the end of this year. Within the scope of the existing, ongoing collaborations, we believe a further 40 new programs will be started between 2008 and 2011. This makes a grand total of 90 partnered programs, and our internal pipeline projections are based on this value.

Note that this calculation relies only on the partnerships that are already in place. Every additional partnership we may sign in the future, will add to the number of HuCAL antibodies coming to market. I'd like to emphasize here that we do anticipate entering new partnerships, but solely for the purpose of this calculation, we have assumed no additional deals.

Slide 44: Developmental Success Probabilities

The next step of the estimate relies on our experience with generating HuCAL antibodies and industry data on developmental success rates. Our experience has shown that the probability that we can generate an antibody against a particular target, and meet the criteria required to enter formal pre-clinical development, is at least 80 %. Our data on pre-clinical development suggest the probability that an antibody will successfully complete this phase is 37.5 %. The third aspect is clinical development, and here we rely on the latest data from the Tufts Centre for the Study of Drug Development, which is probably the most reliable source of statistics on the development of pharmaceutical products. These data show that the probability that a bio-therapeutic drug will move from phase 1 development to market is about 30%.

Slide 45: Partnered Programs: Expected Output

We can now apply these probabilities to our partnerships and estimate how many HuCAL antibodies will come to market from existing partnerships, and that number is 9.

We should be careful not to over-interpret this analysis. It is based on a number of assumptions, and of course includes estimates of programs that haven't even started yet.

However the estimate gives you a sense of the future potential of our partnered pipeline, even if no new deals are signed!

Slide 46: MorphoSys Core Technology HuCAL: How We're Exploiting It

The second point I'd like to make is a strategic one, and that is that our AbD Serotec unit is providing a synergy that we believe will be a major source of future value for our therapeutics activities.

The diagram on slide 46 captures pictorially an important synergy between the two parts of our business. Technology development within the therapeutic antibody segment makes HuCAL a more powerful research tool. This makes the technology more and more attractive for customers of our AbD Serotec unit. This in turn helps our sales of research antibodies through the AbD Serotec unit. Furthermore, it enables us to enter potentially valuable research collaborations which provide access to drug targets that in turn feed the therapeutic antibody segment.

Slide 47: Strategic Research Alliance– The Burnham Institute

A deal that we recently closed exemplifies this. I refer to the alliance with the Burnham Institute, one of the leading medically-oriented research institutes in the United States. It is well funded and ranks 5th among all private U.S. research institutes in terms of NIH funding. It also consistently ranks among the top 20 organizations for the impact of its research publications, measured through scientific citations received per publication by the Institute for Scientific Information (SCI). Burnham scientists have contributed to at least 5 approved therapies and several diagnostic tests that are currently in use, plus another 9 innovative therapies currently in clinical testing.

The agreement we have gives scientists at the Burnham Institute rapid access to HuCAL antibodies for research purposes on preferred terms. In return, MorphoSys secures rights to develop any antibodies with therapeutic or diagnostic potential against targets investigated by Burnham researchers.

The Burnham deal was the first example of such an arrangement. We recently entered a second, with a leading Japanese research institute in a three-way deal also involving our Japanese commercial partners Gene Frontier Corporation.

We aim to forge similar agreements with other research institutes. We are convinced that multiple research-based relationships with leading, medically-focused academic institutes will be a more productive way of accessing the targets of tomorrow than building our own target discovery infrastructure in house. Access to innovative new drug targets will make our business model even more lucrative, since it will enable us to offer not only a proprietary antibody technology, but also novel targets to a collaboration. Under this scenario, MorphoSys would itself be the initiator of therapeutic antibody programs, in contrast to our current model in which the 43 ongoing partnered programs were all initiated by our collaboration partners. On a case-by-case basis, we would decide how far to take individual programs before looking for partners for further development. This model offers considerable flexibility as we would control each program.

Slide 48: Key Factors for Future Growth

Both of our business segments are performing well, and prospects for continued growth are very attractive. As I have mentioned, our current partnerships and the status of our pipeline mean that our therapeutic antibodies segment has reached critical mass. On the research products side of the business, attractive strategic synergies are now being realized. Operationally, we expect the AbD Serotec segment to grow faster than the market and therefore, to increase its market share.

The pharmaceutical industry is facing a severe challenge in filling its development pipeline. MorphoSys's success today is based on its ability to act as a source of antibody drugs. Looking to the future, we believe that by:

- Continually improving our technology to enable generation of even better antibody-based substances even faster,
- Proving that HuCAL antibodies are not only effective in pre-clinical assays but also in the clinic, and
- Leveraging our proprietary technology in the research space to source novel targets,

MorphoSys can become an indispensable partner to the pharmaceutical and research communities.

In closing, our goals for this year are as follows:

Slide 50: Goals 2007

Revenues in 2007 will be in the range € 60 – 65 million, split roughly 2:1 therapeutics: research products. This is consistent with our longer-term objective to grow total group revenues by at least 15-20% year-on-year until such time as HuCAL drugs reach the market in 5-6 years time when we would expect that growth to accelerate sharply. For 2007, we project an operating profit of about € 7-10 million.

With regard to the development of our therapeutic pipeline, we aim to file an IND on MOR103 before year-end. Regarding MOR202, we will continue with pre-clinical development, working towards an IND. We anticipate between 1 and 3 new INDs from our partnered programs this year. This development reflects the growing maturity of our pipeline, and we expect the number of INDs to be even higher next year. We project that the total number of active partnered programs will hit 50 in 2007, and will increase steadily thereafter. Although this may sound like a modest increase from the 43 programs currently under way, it includes assumed attrition in pre-clinical development.

The number of active programs is a more important parameter than the number of deals we sign with pharma companies. Based on the demand we continue to see in the industry, and the number of discussions we are currently engaged in, we anticipate an attractive level of deal flow in the years ahead. Predicting timing and scope of such deals is however very difficult and we can therefore give no precise guidance on this point.

In the Research Antibody segment, our goal for the AbD Serotec unit is to increase revenues by 20% over last year and to reach profitability.

A set of important strategic goals for the unit relate to the growing penetration of the HuCAL technology. To this end, we aim to enter at least one new marketing alliance, and also focus on increasing the uptake of HuCAL antibodies in the research community.

In closing, we look forward to another successful year for the company, and to updating you on a regular basis on our progress. Thank you all for your attention.

Speaker: Dr. Claudia Gutjahr-Löser, Head of Corporate Communications

Thank you very much, Dave and Simon. I would like to open the forum now for your questions. I suggest that we start with the people listening by conference call. May I have your first question, please?

Question & Answer Session:

Dr. Hanns Frohnmeyer, LBBW: I have two questions, Hanns Frohnmeyer from LBBW. One is, how sure are you with your projected 40 new programs coming up in 2008-2011? What is the basis of those calculations? The second, if I look at your guidance for 2007 under the assumption that your AbD unit will be profitable with an EBIT margin of about 5-10% and more milestones coming up from the therapeutics section, it seems to me that your EBIT estimates are rather conservative. Could you comment on that please?

Dr. Simon Moroney: I'll take the first part of that question and Dave will take the second part. The estimate of 40 new programs starting between 2008 and 2011 we've taken out of the existing contracts, some of which run to 2011, some of which terminate earlier. In some of those contracts there are precise commitments about how many programs to start year on year. In other contracts there are options. And what we've done is we've combined the commitments that some of those partners have made with an estimate, a conservative estimate I might say, from the options and added those together to come to this number of 40. The total potential number of programs that could be started if you add the committed programs plus all of the options is actually a lot more than 40, but we have only taken a portion of the options to come up with this number of 40. So we actually feel very, very comfortable with that number of 40.

Dave Lemus: Regarding the conservatism of the 2007 projections, I guess the first thing we have to realize is that we're dealing with ranges when we talk about milestones of approximately € 10 million, that could either be nine or it could be more, same with the EBIT margin. I think if you do the math and you realize also that we are doubling our investment in product and technology spend from this year's current € 3 million to approximately € 6 million next year we think it's conservative but not overly conservative.

Daniel Wendorff, West LB: Three questions if I may, the first question regarding the Bayer-Schering situation. You said the Schering deal for Bayer would slip into the Schering deal and that is going to expire at the end of 2007. How confident are you that that can be extended, and if it's not going to be extended what could be the financial impact in terms of rough guidance? Two financial questions regarding the Capex, how do you see that's going to develop in 2007 and the profitability in the AbD segment, do you mainly achieve this by increasing your gross margin or how do you see the EBIT margin of 5-10% develop?

Dr. Simon Moroney: Let me take the first question about Bayer-Schering and then Dave will speak to the financial questions. The original agreement we had with Schering had a provision in it whereby it could be extended until the end of '07, and that's the agreement that the combined Bayer-Schering is now operating under. We're in discussions with them at the moment about going beyond 2007 but at this stage I'm not able or not prepared to comment on the status of those discussions or the likelihood that we could extend that deal or if so under what terms and conditions. It's an ongoing negotiation and our policy is simply not to comment on ongoing negotiations.

Daniel Wendorff: What's the potential financial impact if it's not going to be extended?

Dr. Simon Moroney: I think what we'd say to that point is we've seen in the past that if deals don't get extended that we'd be in a position to replace them with alternative deals that essentially provide cover if you like for gap that's made by that missing deal. So let me just say

that discussions are ongoing, what the terms could be for a potential extension we don't know at this stage but it's not a source of concern for us, let us put it that way.

Dave Lemus: As it relates to the question regarding Capex, this year we had approximately € 4 million worth of CapEx expenditure, we expect in 2007 that number to be reduced down to approximately € 3 million. That's mainly the result of the fact that in 2006 we had capital expenditures in the amount of about € 1.2 million as it relates to the restructuring of the UK Serotec Group. As it relates to the question increasing the result of AbD Serotec, making it more profitable or the AbD segment rather, I think that's a combination of things. Number one we have restructuring costs of about € 1.7 million last year – those restructuring costs are now finished and we expect no further restructuring costs. That will be one effect, another effect of course will be, we expect a slight increase in the gross profit and of course we also expect through optimizing the product portfolio that the business in total will become more profitable. So, not one thing.

Daniel Wendorff: Thank you.

Dr. Martin Possienke, Equinet: Congratulations on therapeutics, I'm sorry that I have to ask again on the other business unit. Restructuring charges of € 1.7 million if I remember correctly it's pretty much in line with your guidance communicated last year. Nonetheless the operating result is significantly below your guidance so there must be something on the operating side as well, maybe you can comment on that? Then in terms of Serotec on a standalone basis, revenue growth is around 10%, am I correct there? Then if I'm correct why is this below industry growth and what is the trigger to bring it to 20% in 2007?

Dr. Simon Moroney: Ok, maybe I can just start with some general comments about that and Dave will comment on the specific financial questions. What you can't forget is that the year 2007 was one of massive upheaval for us in that area of the business, so we consolidated several different operations, we established brand new premises, we had to relocate our manufacturing into those premises, we had to relocate people from two sites in the UK into those premises in the Oxford. That involved significant expense. We took the opportunity to upgrade their premises from something that was, we felt, well below current industry standard to something now that is really not only today's standard but tomorrow's standard. We have a wonderful facility there and we took the opportunity in 2006 to make considerable expense in order to establish that facility and equip it for the future, so it was really a year of establishing that unit in the best possible way that it can perform in the years ahead. I think for that reason what you should really focus in on is the projected performance for this year which will be growth we project of above 20% which is significantly better than the market. If you look at some of the bigger players in the market they're actually growing below 10%, some of the bigger players such as Chemicon, now part of Millipore, and some of the other antibody specialists are growing below 10%. So if we can achieve that goal of growing over 20% we will be growing at twice the rate of the market this year. So I think those will be my general comments but last year was a year of consolidation and we're now positioned to perform substantially better than the market in the years ahead starting this year.

Dave Lemus: Maybe just to comment on the restructuring charges. I think the guidance that we gave in the beginning of 2006 was that restructuring charges would amount to approximately € 1 million – they were almost double that in the form of about € 1.7 million, so that had a big

impact on the performance of the unit. Part of that was due to the fact that the expenses that we actually had in 2006 were higher than expected. Part of it is also that some of these expenses were pooled forward into 2006 as a result of quicker than anticipated integration moving into the building which then resulted in write-offs which we had anticipated back in 2006 to occur early in 2007.

Dr. Martin Possienke: So from an operating point of view everything went as you imagined it at the beginning of the year?

Dave Lemus: Other than the fact that the restructuring costs were substantially higher and also because of that we had lower gross profits. But I think as Simon mentioned we're quite confident that this unit will become profitable this year and without doubt cash positive.

Dr. Martin Possienke: Just another question on this topic if I may. Regarding the guidance for 2007, I think we speak about some € 22 million in terms of revenues for the AbD Serotec segment, so assuming you keep your COGS and your operating costs stable corrected for restructuring, we end up around € 20 million, so all in all you have to keep your COGS and your operating costs stable in absolute terms in order to reach the upper end of your 5-10% EBIT guidance. Do you think it's possible to keep the COGS level stable and operating costs maybe even declining a bit in absolute terms?

Dave Lemus: Are we talking COGS as a percentage stable or COGS in absolute terms stable?

Dr. Martin Possienke: To achieve the upper end of your guidance, you have to keep it stable in absolute terms.

Dave Lemus: It's unlikely that we'll keep COGS stable in absolute terms. We expect that the total cost of the operating unit, not least due to the fact that we've now restructured a number of the units – that chart that we saw there where we went from approximately 10 subsidiaries to now the current 7 – should also significantly reduce costs. We've substantially streamlined the structure of the group which should result in substantial cost savings. So we expect some improvement to happen on the gross margin as I mentioned and we also expect to see substantial improvement beneath gross margin.

Dr. Martin Possienke: But operating costs will decline in absolute terms most likely?

Dave Lemus: We would expect so, yes.

Dr. Martin Possienke: Ok, thanks a lot.

Holger Blum, Deutsche Bank: One question on the SG&A number in the fourth quarter, it seems nearly twice the run rate of previous quarters. Was it due to the restructuring and what should we therefore expect for the future? The second question on your guidance, could you maybe talk a little bit more what is impacting the range? What makes you end up at the lower end versus upper end of the guidance, especially I think you mentioned that you target € 10 million of milestone payments in 2007. Does that imply one or three INDs? The third question would be more longer term maybe on the proprietary pipeline. You said that you haven't had any partnering talks yet. Might that become a topic over 2007 and maybe over the longer term? Would you have a maximum spending for that maybe for 2008, 2009?

Dr. Simon Moroney: Maybe I'll start with that question about the owned pipeline and then Dave will answer the financial questions. We've deliberately not engaged in the last year in discussions on those programs because we wanted to focus on developing and bringing them forward and generating a strong data package. We feel now that in both cases we have two stories there around MOR103 and MOR202 which are sufficiently strong and especially given the willingness or let me say the desperation of pharma to pay big amounts of money for interesting, even early stage drug candidates, we feel that it's now worth bringing those two stories into our meetings with pharma and biotech when we go out and have those meetings. That said we don't need to partner either of those compounds during the course of this year. However as I said during the talk we want to remain flexible. If we have a discussion with a great partner and they indicate that they would be very interested in working together with us to develop one or the other of those compounds, we will entertain that discussion. But our current intentions are to continue with both of those programs for the foreseeable future on our own.

Dave Lemus: Regarding the Q4 SG&A cost increase, yes, you're correct that the increase is mainly attributable to the write-offs and the restructuring costs in association with the AbD unit in Q4. It also had an extra performance bonus based on the excellent year that we had that we paid in 2006. There was a question regarding the impact of IND milestones on the approximately € 10 million worth of projected milestones for the year. What I'm afraid I can't give you today is in that € 10 million to tell you whether or not in our planning one or three IND milestones are included but obviously certainly at least one is as it was this year. In 2006, we had the IND milestone included from Roche. One could perhaps assume that there is some upside in that guidance if we were to achieve the upper end of the three IND filings.

Dr. Simon Moroney: Maybe I should just add a point to that. Predicting when milestones happen in this industry is enormously difficult. When it comes to clinical programs, filing INDs and so on, recall that we have no influence over this at all and we're simply in the hands of our partners there. So we have an idea or a feeling or a sense, but we have no control at all and therefore planning has to have an element of caution in it when we make estimates of when these are going to occur.

Holger Blum: But what is then causing the range, what are the flexible components in that guidance?

Dave Lemus: Partially it's the milestones and partially it's operational performance. The other thing that has a very significant impact on our ability to call revenues mainly on the therapeutic side of the business is the impact of new revenues. That is very, very difficult to determine. Maybe one other point I should make, what we call as performance based payments includes milestones but is not the only thing that is included in that planning. We have a range of different types of payments which we consider performance based payments that can vary. In total for 2007 we expect them to be € 10 million, they're certainly not all made of three IND payments.

Harald Schmidlin, Independent Analyst: You talked 100% about your own company but I would be interested about the markets where you are moving and developing. Have you some imagination of your market where you are active, the antibody company market or how could you define it? Have you some feeling for your market share in this market, how you developed and what is the measure? It is sales, are there other measures which could give you some

feeling that you are outperforming your competitors? Did you move up in your position from let's say place 50 to 20 and do you believe that this will go forward in the coming years?

Dr. Simon Moroney: When we think about these points we have to think about the two units separately, so the therapeutic antibody segment and the research antibody segment. On the research antibody side a lot of our competitors are private companies and it's hard to get precise information about their turnover for example. But as we said during the presentation we believe based on the best information we have that we're in the top 20 worldwide in terms of our position from the point of view of turnover vis-à-vis our competitors. Remember we started this segment in 2003 so we've gone from nowhere in 2003 to a position in the top 20 in 2006, and we of course are aiming to move beyond there. The fact that that segment is growing at faster than the market rate shows you that we're improving our market share in that segment. On the therapeutic antibody segment we know the competitor space extremely well. Two of our biggest competitors have been acquired in the last 18 months, that's Cambridge Antibody Technology and Abgenix. The way we measure our performance here is largely by the number of partnerships that we enter compared with the number of partnerships that our competitors enter. Here we know that we're in the top two, possibly three worldwide in that segment. I think if you look at the top 20 pharma companies, we're number one in terms of the number of partnerships we have signed over the last 3-4 years. So that's the basis of our claim that we are the partner of choice for people who are prepared to pay serious money for access to a technology. MorphoSys is the partner of choice, that's a perfectly fair statement based on the deals that we've signed over the last couple of years.

Harald Schmidlin: Just one additional question. The antibody technology is one of several technologies to develop new products. Do you feel that this technology will become even more important or if you look to GPC's Satraplatin, I think it's not antibody, it's something different so there are other methods and other technologies, biotechnologies. Do you think the antibody technology will become more important or could lose some importance?

Dr. Simon Moroney: That's a good question. I'm convinced that it will become more important and the reason why is you just have to look at the level of interest in the pharmaceutical industry. Ten years ago or 15 years ago there were no antibody drugs, perhaps one 15 years ago. Today there are 20. There are well over 100 in clinical trials today, and those of course are the products of tomorrow. So the level of interest in the pharmaceutical industry for this class of drugs, for antibodies as a class has exploded in the last five years and based on the discussions and negotiations that we continue to have in the industry we see that growth going on out into the future. Whenever we talk to potential partners and of course our existing partners – the Pfizers, the Novartis, the Roches, the Bayer Scherings, the Centocors, the Lillys, the Schering Ploughs, all these people – we ask them a question that's of great importance for us which is how much of a future do antibodies and antibody technologies have because we worry about that, it's importance for us. The answer we always get back from those people is 15, 20 years and beyond. This is not something that's going to come to an end tomorrow. This is something that the industry is committed to, that they're putting big investments into and the proof of that point is the fact that as we said in the presentation for Novartis, 1/3 of their pre-clinical biologics pipeline comes out of our technology. That's a big bet that Novartis is placing on their future portfolio of products which is directly based on our technology. So we feel very, very comfortable and confident about the importance of our technology and MorphoSys in the future of this industry.

Siegfried Hofmann, Handelsblatt: I just want to ask a question about the conditions of your pharmaceutical collaborations in light of the huge interest of the big pharma companies in antibodies. How does it translate into the conditions of your deals you are doing and do you see any shifts in the mix between up front payment milestones and royalties?

Dr. Simon Moroney: That's a good question. Several years ago we had to face the criticism that all this stuff would become a commodity and would be worth nothing, and we've seen that in the case of for example combinatorial chemistry libraries where in the late 90s they were something that you could charge milestones and royalties for, and then a few years later if you got a little bit of up front cash you were very lucky. So the criticism that people pointed at us five years ago that our technology would become a commodity has absolutely not panned out at all, and the fact of the matter is that although terms and conditions haven't improved, they haven't decreased at all. So in broad terms the royalties and the milestones that we can demand today are pretty much the same as they were five years ago, meaning that the technology has held its value. There are limits to what you can charge because if you think about royalties for example, the pharma company does a calculation of how much they can afford to pay in terms of royalties and there is a limit on that number. But I think the fact that we've been able to hold those financial terms stable over that period is proof of the fact that the technology has retained its value and not become commoditized.

Daniel Wendorff, West LB: Maybe one follow-up question regarding your own antibody development programs. You mentioned that the Burnham Research Institute collaboration could present a sort of precedent for how you might even expand that further. How likely is it that you're going to expand that beyond the two programs, so within the next 1-2 years?

Dr. Simon Moroney: It depends on the targets we see emerging. The reason we believe that this is a better way to source targets is that target discovery is enormously unpredictable, and we've even seen that at our pharma partners that some of them have moved out of target discovery in-house because you cannot predict if you study 100 targets how many of them will actually turn into real drug targets. So for us it's very difficult to say that Burnham will supply 1 or 3 or 5 or that any other institute will be a source of a certain number. However we believe it's a numbers game, the more collaborations you have, the more interesting programs will emerge. You shouldn't expect that we're suddenly going to be pursuing 10 proprietary drug programs within the next year, that's not going to happen. The number will remain modest, but we always hope that we can start additional programs but it's based on the quality of the target we see finally.

Daniel Wendorff: You don't have a limit to the upper end sales this way? Say if four very interesting targets turn up you would potentially try to pursue all four?

Dr. Simon Moroney: Of course we do have a limit because it comes back to R&D investment, but again our preparedness to invest in these programs is based on the quality of the target. If we identify targets that are extremely interesting we're going to be more inclined to invest in those than if we don't do that. So it really depends on the quality of the targets that are fed into the process.

Dave Lemus: Maybe if I could just add some color to that, of course we're also constrained financially by what we can afford and I think as we've stated before it's not our intention to go back into loss.

Daniel Wendorff: Ok, thank you.

Thomas Schiessle, Equits: Gentlemen, a question on the regional structure of your business. You're active in the Norwegian region, I think it's not a hotspot of the antibody business but you aren't in Japan. Could you please give us some colour on your next steps in the Asian region and what this Hamar business is about? The other one is an additional question to the Burnham Institute. Is this really the new strategy to get in touch with new validated targets to fill the internal pipeline for MorphoSys? Is this the lesson of the last three years? Thank you.

Dr. Simon Moroney: First of all Thomas thank you for that question. Regarding Hamar in Norway. The sales office there is a Scandinavian sales office. It happens to be in Hamar because the principle happens to live in Hamar. It's not because that's the centre of Norwegian research activity, it's a Scandinavian sales office. With respect to the other regions of the world we feel that we're very well served by a series of distributor relationships particularly in the Japanese market where direct selling to the customer is essentially unknown. In contrast to Europe and the US where you can sell direct to the customer, in Japan the traditional structure is that you have to go through a distributor. Universities and research institutes will have established relationships with distributors and you basically cannot sell direct to the institute researcher, you have to go through the distributors, it makes sense to stick with that system.

Regarding the Burnham, maybe just to give all of you a bit more colour on this. Some of the most exciting feedback we have received from pharma companies in the last few months has been based on our relationship with the Burnham Institute. Pharma companies themselves struggle to find interesting new targets. There's a belief in the industry that the new targets are being discovered in academia, and therefore for us to have a preferred relationship with a leading institute like this where we have traded access to HuCAL technology for rights to targets that they discover, pharma companies have spotted this and have been extremely interested in the relationship because that's the kind of thing that they think is going to source the targets of tomorrow. We're looking to do more of these as I said. It won't be 100 because we're looking to do it in a very targeted way where we identify medically focused research institutes with whom we'll do such relationships. We found a second one with a Japanese research institute that for confidentiality reasons we're not allowed to name and we're currently in further discussions. So we think that that's an extremely interesting potential source of new targets for ourselves.

[Question made off microphone]

Dr. Simon Moroney: The question was how many targets can we digest? The discovery work is not being done at MorphoSys. It's being done at the research institutes. Our initial role in this is supportive and observing what goes on there, and when we see interesting projects that we feel that we want to bring in-house and start to develop therapeutic antibodies against those targets we can do so. As we said to Daniel before this is not something at this stage we want to put a concrete number on, but certainly in the earlier stages it's cheaper obviously, we can pursue

rather more programs. As programs move forward and it gets more expensive then we have to look at how much we're prepared to invest.

Dr. Karl-Heinz Scheunemann, Bankhaus Metzler: Thank you. I've a couple of questions concerning MOR103. Unfortunately we could learn from the presentation that you again will not share with us the biological target of the molecule. Could you give us a reason for this or at least when will we get some more information on the characteristic of the molecules? The last one is: Would I be completely wrong if I would assume it's not an anti-TNF project?

Dr. Simon Moroney: Let me start by answering the second question. We, actually in this room, one year ago answered that question when we said that the target was not TNF, so that's no new news. That news is one year old now. The other question is why are we not naming it and when will we name it? I would love to tell you about it because we think it's a great target, we think it has been overlooked and we're very excited about it. But there are competitive reasons why we don't do that and we don't want to awaken potential competitors and have them jump on the same target, so although we'd love to share it with you we don't want to run the risk that our competitors could find out what this program is. As soon as we feel comfortable with that competitive issue we'll tell you because we would like to communicate it because we think it's a great story, but we have to be careful of our competitive situation.

Dr. Martin Possienke: Just as a follow-up, to your knowledge is there anybody else working on this target?

Dr. Simon Moroney: We can't rule it out because we don't know what other people are doing either.

Dr. Martin Possienke: So you know about no-one is working on?

Dr. Simon Moroney: I would be very surprised if no-one else was working on it, I'd be very surprised about that because this is not a leap in the dark for us. This is not some totally new gene that someone has just identified for which there is no evidence that it could be a rheumatoid arthritis gene. There is evidence available and given that is the case it's highly likely that there is at least one other party working against that target.

Dr. Martin Possienke: Ok, thanks.

Thomas Schiessle: Simon, could you please update us on your IP position and your efforts to strengthen it and be more powerful in the future?

Dr. Simon Moroney: Do you mean in general terms around the technology or specific programs or...?

Thomas Schiessle: In general and the IP position concerning HuCAL, HuCAL GOLD and expiry dates and so on an so forth? Thank you.

Dr. Simon Moroney: The underlying patent on the HuCAL technology will run until 2015 or so, but in all of the areas whether it's technology or whether it's specific products, either partner products or owned products we routinely look to create new intellectual property through patent filings. Just to give you an example, in many of our partnerships many of the targets that we're

working on are public domain targets. The partners whoever it may be are pursuing those targets even though those targets have no patent protection on the target itself. In almost all of those cases we're able to create a proprietary position around the program even though the target may be a public domain target by patenting some feature of the antibody for example, its epitope specificity or some surprising feature that emerges during the development of the program. We have an in-house patent department that's actually headed by an American patent attorney and I would say in general we've become much more aggressive in pursuing patent protection for technologies and product candidates than we were in the past.

Thomas Schiessle: If it comes to production of antibodies, I guess you have a collaboration with Crucell for clinical quantities and there is some development partnership with Wacker Chemie I guess, but that's not for testing quantities, it's for the commercial quantities, isn't it. What is the status of the partnerships?

Dr. Simon Moroney: The Crucell relationship is kind of a triangular relationship which also involves DSM and is based on a research agreement we signed with Crucell a couple of years ago to test their PER.C6 cell line, this human cell line and we're now using that cell line at DSM to produce clinical material for the MOR103 Phase I clinical trial. Some of you may have seen that Crucell put out a press release recently that they reached 10 grams per litre of antibody produced using the PER.C6 system, so we think that that system is very attractive for two reasons. One is that you get human glycosylation patterns on your antibody, and the second and perhaps even more interesting is that the yields are enormous. So that's a very attractive commercial aspect to the system. The Wacker relationship is more of a discovery or research relationship to test systems mainly for the production of fragments, antibody fragments, and that is primarily aimed at the AbD side of the business trying to look for improved systems with better efficiency for making antibodies for the research community. As I said it's primarily a research and investigative study that we're carrying out with them at this stage.

Dr. Claudia Gutjahr-Löser: Ok. If there are no further questions here or from the conference call then I would like to conclude today's conference. We thank you all for your participation. Good Bye.